

The Textbook of Non-medical Prescribing addresses all the key issues relevant to non-medical prescribing, bringing together essential knowledge, key issues, and skills in a single text.

This accessible, engaging and comprehensive resource explores: the history of non-medical prescribing; prescribing in context; ethical, legal and professional issues in relation to prescribing practice; factors influencing prescribing; effective consultations; essential pharmacology; the role of the multi-disciplinary team; clinical skills; prescribing for specific groups; and the future of nurse prescribing. With case studies throughout, *The Textbook of Non-medical Prescribing* will be essential reading for all students on non-medical prescribing courses. It will also be of use to qualified health professionals, be they prescribers themselves or interested in the concepts of non-medical prescribing.

KEY FEATURES:

- An essential core text for students on non-medical prescribing courses
- Accessible, lively and interactive in style
- Student-friendly, including learning objectives, activities, and case studies, enabling readers to apply prescribing principles to practice
- Interactive companion website www.wiley.com/go/nuttall

For extra resources, please visit the companion website for this book, featuring:

- multiple choice questions
- case studies
- numeracy exercises
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ABOUT THE EDITORS:

Dilyse Nuttall is Senior Lecturer in the School of Nursing and Caring Sciences at The University of Central Lancashire, where she is course leader for the Non-medical Prescribing programme.

Jane Rutt-Howard is Senior Lecturer in the School of Nursing and Caring Sciences at The University of Central Lancashire, where she is course leader for both MSc Professional Practice (Nurse Practitioner) and BSc (Hons) Nurse Practitioner programmes.

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THE TEXTBOOK OF NON-MEDICAL PRESCRIBING

DILYSE NUTTALL | JANE RUTT-HOWARD

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Edited by
Dilyse Nuttall

MSc (by research), PGDip, BSc (Hons), RN, RHV
Nurse Prescriber, Nurse Teacher, NMC registrant, Fellow of Higher Education Academy, Senior Lecturer, School of Nursing and Caring Sciences, University of Central Lancashire, Preston, Lancashire
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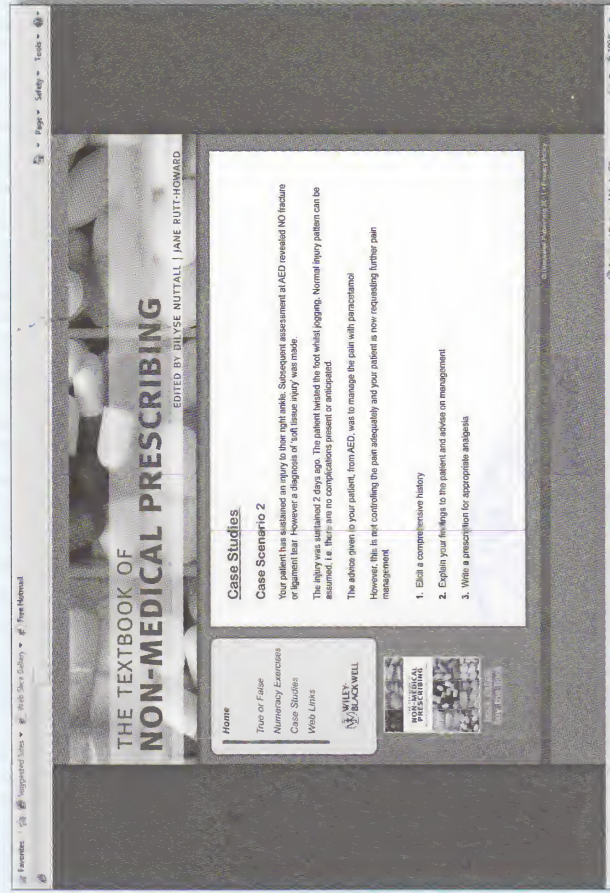
Jane Rutt-Howard

MSc, BSc (Hons), Dip HE, RGN
Nurse Prescriber, NMC registrant, Associate Fellow of Higher Education Academy, Senior Lecturer, School of Nursing and Caring Sciences, University of Central Lancashire, Preston, Lancashire



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2121 State Avenue, Ames, Iowa 50014-8300, USA

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Contributor List

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Gillian Armitage, BSc(Hons), RN Nurse Teacher, NMC registrant, Senior Lecturer, School of Nursing and Caring Sciences, UCLAN, Preston, Lancashire	328
Alison Astles, BPharm(Hons), Dip Pres Sci, MRPharmS Pharmacist Practitioner/Teacher Practitioner, School of Pharmacy, UCLAN, Preston, Lancashire	329
Ruth Broadhead, LLM (Master of Laws, Medical Law & Bioethics), BA(Hons), RGN, PGCert, DipHE (Specialist Practitioner) V300 Independent & Supplementary Prescriber, NMC registrant, Senior Lecturer, UCLAN, Preston, Lancashire	330
Janice Davies, MSc, BSc(Hons), MRPharmS Pharmacist Practitioner/Teacher Practitioner, School of Pharmacy, UCLAN, Preston, Lancashire	331
Dawn Eccleston, MSc, BSc, RN, RHV, PGCertEd, NP NMC registrant, Fellow of Higher Education Academy, Senior Lecturer, School of Nursing and Caring Sciences, UCLAN, Preston, Lancashire	332
Anne Fittock, MSc, BPharm(Hons), PGD, PGCertEd, MRPharmS Fellow of Higher Education Academy, Senior Pharmacist, Medicines Management Team, Public Health Offices, East Lancashire PCT	333
David Kelly, MPharm, MRPharmS Independent Prescriber, Pharmacist Practitioner/Teacher Practitioner, School of Pharmacy, UCLAN, Preston, Lancashire	334
Val Lawrenson, BA(Hons), MEd, CPT, RN, DN, NP Nurse Teacher, NMC registrant, Senior Lecturer, School of Nursing and Caring Sciences, UCLAN, Preston, Lancashire	335
Anne Lewis, MSc, BNurs, RN, RHV, DNcert NMC registrant, Trust Prescribing Lead, Central Lancashire PCT, Preston, Lancashire	336

Dilyse Nuttall, MSc (by research), BSc(Hons), PGDip, RN, RM, RHV
Nurse Prescriber, Nurse Teacher, NMC registrant, Fellow of Higher Education Academy, Senior Lecturer, School of Nursing and Caring Sciences, UCLAN, Preston, Lancashire

Joseph Quinn, MSc, BScPharm(Hons), MRPharmS
Member College Pharmacy Practice, School of Pharmacy, UCLAN, Preston, Lancashire

Jane Rutt-Howard, MSc, BSc, Dip HE, RGN
Nurse Prescriber (V300), NMC registrant, Assoc. Fellow of Higher Education Academy, Senior Lecturer, School of Nursing and Caring Sciences, UCLAN, Preston, Lancashire

Jean Taylor, MSc, BA(Hons), RN, RM, RHV
Nurse Teacher, NMC registrant, Fellow of Higher Education Academy, Principal Lecturer, School of Nursing and Caring Sciences, UCLAN, Preston, Lancashire

Samir Vohra, BPharm, MRPharmS
Lecturer in Clinical Pharmacy Practice, School of Pharmacy, UCLAN, Preston, Lancashire



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Introduction

Dilyse Nuttall and Jane Rutt-Howard

The *Textbook of Non-Medical Prescribing* has been developed to provide the reader with an insight into the key issues relating to prescribing in the UK today. The book's team of authors have vast experience in the development and delivery of non-medical prescribing programmes. This book has been developed in response to needs of health professionals undertaking the non-medical prescribing programme, and to the views of qualified non-medical prescribers and their colleagues.

The aim of the book is to:

- 1 provide a foundation on which non-medical prescribing students (V100, V150 and V300 including nurses, pharmacists and allied health professionals) can build their knowledge around the key areas and principles of prescribing
- 2 act as a continued source of information for qualified non-medical prescribers
- 3 provide a key source of information for non-prescribing health professionals who need to learn about the concept and context of prescribing in modern healthcare (e.g. pre-registration student nurses, pre-registration health professionals, including doctors considering acting as designated medical practitioners, who need to understand more about their role and the context of non-medical prescribing).
- 4 provide a key source of information for prescribing health professionals, including doctors considering acting as designated medical practitioners, who need to understand more about their role and the context of non-medical prescribing.

This book provides information essential to enable safe and effective prescribing. It also supports and directs the development and expansion of the reader's knowledge base, using generic principles to underpin specialist practice. The introduction has a dual purpose: to introduce the reader to the involvement of non-medical prescribing and its position in a modern, multidisciplinary health service and to provide guidance on using the book effectively.

The development of prescribing

It had long been recognised that nurses wasted a significant amount of time visiting general practitioner (GP) surgeries and/or waiting to see the doctor in order to get a prescription for their patients. Although this practice produced the desired result of a prescription being generated, it was not an efficient use of either the nurses' or the GPs' time. Furthermore, it was an equally inefficient use of their skills, exacerbated by the fact that the nurse had usually assessed and diagnosed the patient and decided on

an appropriate treatment plan. The situation was formally acknowledged in the Cumberlege Report (Department of Health and Social Security 1986) which initiated the call for nurse prescribing and recommended that community nurses should be able to prescribe from a limited list, or formulary. Progress was somewhat measured but *The Crown Report of 1989* (Department of Health (DH) 1989) considered the implications of nurse prescribing and recommended suitably qualified registered nurses (district nurses (DN) or health visitors (HV)) should be authorised to prescribe from a limited list, namely the nurse prescriber's formulary (NPF).

Although a case for nurse prescribing had been established, progress relied on legislative changes to permit nurses to prescribe. Progress continued to be cautious with the decision made to pilot nurse prescribing in eight demonstration sites in eight NHS regions. In 1999, *The Crown Report II* (DH 1999) reviewed more widely the prescribing, supply and administration of medicines and, in recognition of the success of the nurse prescribing pilots, recommended that prescribing rights be extended to include other groups of nurses and health professionals. By 2001, DNs and HVs had completed education programmes through which they gained V100 prescribing status, enabling them to prescribe from the NPF. The progress being made in prescribing reflected the reforms highlighted in *The NHS Plan* (DH 2000), which called for changes in the delivery of healthcare throughout the NHS, with nurses, pharmacists and allied health professionals being among those professionals vital to its success. The publication of *Investment and Reform for NHS Staff - Taking forward the NHS plan* (DH 2001) stated clearly that working in new ways was essential to the successful delivery of the changes. One of these new ways of working was to give specified health professionals the authority to prescribe, building on the original proposals of *The Crown Report* (DH 1999). Indeed, *The NHS Plan* (DH 2000) endorsed this recommendation and envisaged that, by 2004, most nurses should be able to prescribe medicines (either independently or supplementary) or supply medicines under patient group directions (PGDs) (DH 2004).

After consultation in 2000, on the potential to extend nurse prescribing, changes were made to the Health and Social Care Act 2001. The then Health Minister, Lord Philip Hunt, provided detail when he announced that nurse prescribing was to include further groups of nurses. He also detailed that the NPF was to be extended to enable independent nurse prescribers to prescribe all general sales list and pharmacy medicines prescribable by doctors under the NHS, together with a list of prescription-only medicines (POMs) for specified medical conditions within the areas of minor illness, minor injury, health promotion and palliative care. In November 2002, proposals were announced by Lord Hunt, concerning 'supplementary' prescribing (DH 2002). The proposals were to enable nurses and pharmacists to prescribe for chronic illness management using clinical management plans. The success of these developments prompted further regulation changes, enabling specified allied health professionals to train and qualify as supplementary prescribers (DH 2005).

From May 2006, the nurse prescribers' extended formulary was discontinued and qualified nurse independent prescribers (formerly known as extended formulary nurse prescribers) were able to prescribe any licensed medicine for any medical condition within their competence, including some controlled drugs. Further legislative changes allowed pharmacists to train as independent prescribers (DH 2006) with optometrists gaining independent prescribing rights in 2007. The momentum of non-medical pre-

scribing continues, with 2009 seeing a scoping project of allied health professional prescribing, recommending the extension of prescribing to other professional groups within the allied health professions and the introduction of independent prescribing for existing allied health professional supplementary prescribing groups, particularly physiotherapists and podiatrists (DH 2009). As the benefits of non-medical prescribing are demonstrated in the everyday practice of different professional groups, the potential to expand this continues, with consultation being recently undertaken to consider the potential for enabling other disciplines to prescribe (DH 2010).

Using *The Textbook of Non-medical Prescribing*

Overview

Each of the nine chapters contained within this book addresses a different issue; all of the issues are directly relevant to non-medical prescribing, so it is therefore recommended that the reader peruses all the chapters to gain a full insight into non-medical prescribing. However, it is not necessary to read the chapters in numerical order. The issues and principles considered within each chapter are generic to all prescribing and it is anticipated that the reader will apply this theory to his or her own practice. This will be helped by undertaking the activities incorporated within each chapter. Where appropriate, and in order to support the reader's understanding, references are made within individual chapters to other chapters in the book.

Core themes

The book has three core themes - public health, social and cultural issues and prescribing principles - which are considered significant both to safe and effective prescribing and to modern healthcare in the UK. The core themes are incorporated into the main body of each chapter and considered at the end of every chapter in a Key themes and considerations box. These core themes are:

Public health
Social and cultural issues
Prescribing principles

It is pertinent at this point to introduce the prescribing principles (National Prescribing Centre (NPC) 1999) because it is recognised that this may be a new concept to the reader. These were developed originally to support the first nurse prescribers in their decision-making but have continued to be an essential tool in supporting prescribers from all health professional groups able to prescribe. The 'seven good principles of prescribing' were developed by the NPC (1999) with the aim of providing a structured approach to the process of prescribing.

The principles are 'a stepwise approach' and are widely used both theoretically and practically. They are diagrammatically represented within the original *Prescribing Nurse Bulletin* (NPC 1999) as a pyramid. It could be suggested that the use of a pyramid to illustrate a 'stepwise approach' is not particularly representative. The connotation of a

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pyramid suggests a hierarchy of activity. All the principles of prescribing are as important as each other and may be better represented by the use of a staircase – there is an order to the principles (Figure 1.1).

Each of the seven principles requires the practitioner to have specific skills to support the prescribing process and to consider the relevant issues at each stage:

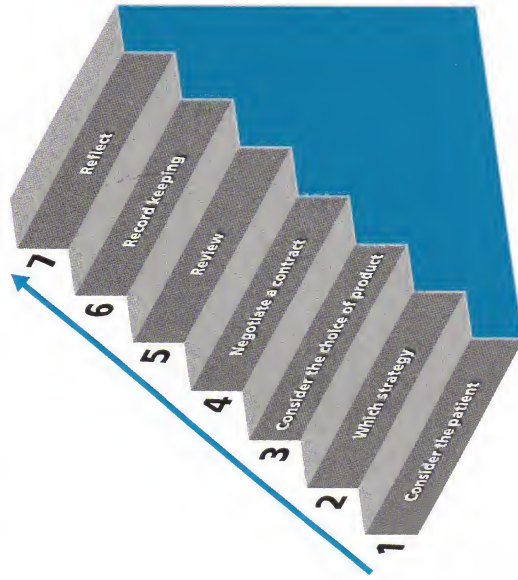


Figure 1.1 A 'step wise' diagrammatical representation of the 7 Principles of Good Prescribing (NPC 1999).

Principle 1: examine the holistic needs of the patient

This requires the non-medical prescriber to make a thorough assessment in order to determine the appropriate course of action. This is aided by the use of the mnemonic 2-WHAM (NPC 1999):

- W** – who is it for/who is the patient?
- W** – what are the symptoms?
- H** – how long have the symptoms been present?
- A** – action taken so far?
- M** – other medication?

Principle 2: consider the appropriate strategy

This highlights that the generation of a prescription is only one option and other treatment options might be more appropriate than drugs in some instances. Equally, to ensure that a prescribed treatment is most effective, it may need to be used alongside another strategy such as health promotion or referral to another health professional.

Principle 3: consider the choice of product

This prompts the prescriber to ensure that the product prescribed is that most appropriate for the patient, considering the clinical and cost-effectiveness. The NPC (1999) developed the mnemonic EASE to assist this process:

- E** – how clinically effective is the product?
- A** – how appropriate is the product for this specific patient?
- S** – how safe is it?
- E** – is the prescription cost-effective?

Principle 4: negotiate a contract

This stresses the importance of involving the patient in decision-making in order to achieve concordance with the patient. The treatment option eventually undertaken should be the result of negotiation between the patient and prescriber, taking into account the patient's views, experiences and expectations.

Principle 5: review the patient

This requires that the prescriber maintain prescribing safety by regularly reviewing the patient to ensure that the treatment remains effective and appropriate.

Principle 6: record keeping

This reiterates the importance of accurate and up-to-date records in prescribing.

Principle 7: reflect

This acknowledges the importance of reflection in enabling the prescriber to maintain competence and continue to develop professionally.

Learning objectives

Each chapter has its own set of learning objectives that underpin its content. Achievement of these learning objectives is supported by both engagement with the discussion within the main text of the chapter and undertaking the activities.

Activities

Throughout the book are activities that support the reader in developing a deeper understanding of the theoretical knowledge base and in the application of theory to individual practice. Activities are present throughout the book and are indicated by the blue activity sign:



Case studies

The use of this book is supported by case studies at the end of the book. Most of the chapters make reference to a number of the case studies provided. This may be as part of the discussion or as an activity within the chapter. The purpose of the case studies

is to help the reader to appreciate the benefits of non-medical prescribing both to the patient and to the different professions. Two groups of case studies are included: patients and health professionals. The patient case studies are numbered 1-9 and form the basis of many of the activities. The health professional case studies are annotated A-J and, in the main, serve to provide relevant examples of the use of non-medical prescribing by the different professional groups able to prescribe, from both an independent and a supplementary perspective.

Chapters and content

Chapter 1: Prescribing in context

This chapter defines and discusses the concept of non-medical prescribing in the context of a modern UK health service. It explores the different qualifications available in non-medical prescribing and discusses their application in the practice of various professionals, including nurses, pharmacists and allied health professionals. This chapter includes explanation of independent, supplementary, community practitioner, V300, V150 and V100 prescribing. It also explores pharmacist and allied health professional prescribing. Comparisons are made between the different types of prescribing to highlight their individual benefits and restrictions.

Chapter 2: Ethical, legal and professional issues in relation to prescribing practice

The development of non-medical prescribing has depended on changes in professional body regulations, legal frameworks relating to medicines, and attitudes of patients and professionals in relation to roles and responsibilities. This chapter explores the ethical issues that impact on safe and effective prescribing. It also identifies the legal frameworks governing prescribing for all professional groups, highlighting the changes undertaken to enable and support non-medical prescribing. The extension of prescribing to other professional groups meant that the professional bodies had to develop existing regulations and guidance to support and govern this element of practice. This chapter explores these issues, identifying common elements of best practice, including prescription writing.

Chapter 3: Factors influencing prescribing

In addition to ethical, professional and legal issues, non-medical prescribing is subject to a variety of other influences that impact on the non-medical prescriber's ability to prescribe safely and effectively. This chapter explores these issues and identifies strategies to overcome related difficulties in order to promote concordance. The issues discussed include patient expectation, media influences, professional conflicts, drug company representatives, competence and training.

Chapter 4: Effective consultation

Chapter 4 discusses the holistic needs of the patient, considering these within the framework of existing consultation models. The various elements of the consultation process are explored, focusing on history taking and physical examination in relation to prescribing. The consultation culminates in the development of a management plan and this chapter explores the strategies used to enable this, including clinical decision-

making. The chapter incorporates an analysis of clinical decision-making models and theories, from both non-medical and medical perspectives. It also explores the consideration that all practitioners will experience a shift in their practice in order to address the novice aspect of prescribing. The deconstruction of their own practice can be difficult to manage both personally and professionally.

Chapter 5: Essential pharmacology

It is recognised that individual practitioners cannot know everything about all medicines but an essential element of good prescribing practice is *learning how to find out what we need to know*, in order to prescribe safely. This chapter directs the reader to trusted resources to develop and maintain knowledge about drugs. It guides the reader through processes to build a relevant knowledge of pharmacology, therapeutics and medicines management to populate his or her own personal formulary. Non-medical prescribing is founded on the principle that practitioners will prescribe only within their competence and scope of practice. It is an essential component of the clinical competence of prescribers to have knowledge of both how the drugs that they prescribe work at their site of action and how the drugs are handled by the body. The significance of co-morbidity and drug interactions is discussed, as are adverse drug reactions (ADRs), in order that the non-medical prescriber can minimise the risk to patients. The drug that the patient doesn't take is the most expensive drug of all. Patients can pay a high price in unresolved illness and lost earnings, while the NHS wastes valuable resources. This chapter discusses issues of concordance and adherence and guides the reader through processes by which negotiated consultations are encouraged.

Note that the principles of pharmacology addressed within this chapter aim to equip those practitioners with limited pharmacological knowledge with a foundation on which to build their understanding of the key issues.

Chapter 6: The multidisciplinary prescribing team

An essential aspect in safe and effective prescribing is recognition that prescribing is undertaken in a multidisciplinary context. This chapter examines the meaning of multidisciplinary team working in prescribing and explores the roles of the team members. The support processes provided by the various prescribing team members to individual non-medical prescribers, in a variety of situations and circumstances, are discussed.

Chapter 7: Clinical skills

Comprehensive and holistic assessment requires the use of appropriate clinical skills in order to support clinical decision-making and diagnosis. This chapter explores those skills recognised as core to safe and effective prescribing, highlighting relevant resources that can be accessed to incorporate these skills effectively. It is also recognised that a vast array of clinical skills, other than those considered core, will be used by non-medical prescribers in order to support prescribing in their specialist area of practice. Strategies to identify and develop these skills are discussed, emphasising the requirement for individual non-medical prescribers to prescribe within their competence.

Chapter 8: Prescribing for specific groups

It is recognised that different groups, such as children, older people, pregnant and breastfeeding women, and those with hepatic and renal impairment, require specific

attention to ensure that the physiological differences and related risks are recognised and considered when prescribing. This chapter explores the needs of these individual groups in relation to prescribing, making reference to relevant guidance to support the non-medical prescriber in safe and effective prescribing. In addition to the groups mentioned, it is also recognised that other groups have specific needs that can impact on the ability of the non-medical prescriber to prescribe safely and effectively. These groups include young people, men, travelling families and black and minority ethnic groups. This chapter examines the needs of these specific groups in relation to prescribing practice.

Chapter 9: Enhancing non-medical prescribing

Non-medical prescribing has continued to evolve, enabling more groups of professionals to prescribe a wider range of drugs. However, the development of non-medical prescribing will continue as the number of prescribers increases. To support this process, infrastructures are necessary at all levels. The development of guidelines and policies to enable the non-medical prescriber to practise is only one aspect of a wider organisational approach. This chapter explains this infrastructure and discusses how it supports non-medical prescribing and promotes its development. The continuing professional development of individual practitioners is paramount and supported by reflection, identifying learning objectives and planning for professional development. This chapter explores the strategies in place to support this process.

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Chapter 1 Prescribing in Context

Dilysse Nuttall

Learning objectives

After reading this chapter and completing the activities within it, the reader will be able to:

- 1 identify the development and current context of non-medical prescribing in the UK
- 2 critically analyse the implementation of non-medical prescribing in relation to the different professional groups
- 3 evaluate the different types of prescribing and identify their appropriate application to practice

Non-medical prescribing has been subject to on-going development ever since its inception. This has resulted in changes in both the types of prescribing possible and the related terminology. This chapter explores the different qualifications available in non-medical prescribing and discusses their application in the practice of various professionals, including nurses, midwives, pharmacists and allied health professionals. The discussion incorporates explanation of independent prescribing and supplementary prescribing, differentiating between specific prescribers and making comparisons to highlight their individual benefits and restrictions.

The prescribing journey

The current position of prescribing is the result of its evolution from its origin in district nursing and health visiting to a well-established element of everyday practice for a range of health professionals. The journey has not been as straightforward as many would have hoped, with individual professions having to undertake a period of limited prescribing before being able to use it in a manner that best supports their practice. The introduction of prescribing to the nursing profession was, in many ways, tentative,

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with the 1992 Medicines Act enabling only a small group within a very large workforce to undertake the necessary programmes of education. Furthermore, the limited formulaary imposed a controlled and constrained introduction of prescribing. Nevertheless, this was a welcome development, the benefits of which became increasingly apparent and, ultimately, led to prescribing becoming available to more nurses and more professions.

Arguably, the caution employed in the introduction of prescribing in nursing was, in part, due to the lack of a robust evidence base to support this new element of practice. Although many nurses' perceived intimidation from this cautious approach was that they were more likely to make mistakes, a view unfortunately held by some medical colleagues (Day 2005), the profession was able to develop an increasing evidence base to support the expansion of prescribing. Supported by government-led consultations and evidence gathering from other professional groups and professional bodies, the necessity to introduce prescribing to other professional groups dictated the apposite change in terminology from nurse prescribing to non-medical prescribing.

Defining non-medical prescribing

The issue of terminology has often caused discord and confusion. The term 'nurse prescribing' remains an accurate description for nurses, with prescriptions continuing to identify nurses as such. Similarly, the terms 'pharmacist prescriber' and 'allied health professional prescriber' are used by the professional bodies governing these groups (Health Professions Council (HPC) 2006, Royal Pharmaceutical Society of Great Britain (RPSGB) 2006). Furthermore, the Departments of Health in England, Scotland, Wales and Northern Ireland (Department of Health (DH) 2006a, 2006b, Department of Health, Social Services and Public Safety (DHSSPS) 2006, Scottish Executive Health Department (SEHD) 2006, Welsh Assembly Government 2007, NHS Scotland 2009) continue to differentiate between prescribers. As a result, these terms are reiterated in the names of education programmes and in the evidence base supporting prescribing. Indeed, there is much benefit in this differentiation, from both a safety and a professional development perspective. However, these individual practitioner titles are components of the

Activity box 1.1

Go to the government website relevant to your practice area and search for documents that outline the implementation of non-medical prescribing for your professional group. Consider their content in relation to your practice:

- www.dh.gov.uk
- www.scotland.gov.uk
- www.wales.gov.uk
- www.dhsspsni.gov.uk

broader context of prescribing by those health professionals who are not doctors or dentists. The inclusive term 'non-medical prescribing' is now widely used to represent these prescribers. It may be argued that the use of yet another term serves only to add further confusion, particularly to those unfamiliar with the concept of non-medical prescribing. However, the disadvantage of making reference only to individual titles is that there is much potential to support a profession-based approach that detracts from the multidisciplinary approach required for safe and effective prescribing, highlighted in Chapter 6.

The non-medical prescribing vision

In considering the context of non-medical prescribing, it is of benefit to revisit the origins of nurse prescribing to consider its early ethos and vision. The *Review of Prescribing and Administration of Medicines: Final Report* (DH 1999a) identified five key principles within the terms of reference (Table 1.1). On examining these principles and making comparison to policy and guidance supporting the current position of non-medical prescribing, it is evident that these principles remain steadfast. The Department of Health (2008a), in the document *Making the Connections: Using healthcare professionals as prescribers to deliver organisational improvements*, clearly identified the benefits of non-medical prescribing and the opportunities for healthcare professionals to enhance their practice by making effective use of prescribing. The benefits of non-medical prescribing presented for patients included increased access, increased capacity and improved choice for patients. This was supported by the professionals' ability to manage and complete episodes of care for patients, in a variety of settings, reiterating the messages from *Medicines Matters* (DH 2006b). Although the terminology and focus may have shifted slightly, the underpinning principles remain the same: safe and effective prescribing.

The complex nature of good prescribing was identified by the National Prescribing Centre (NPC) when they released their first *Nurse Prescribing Bulletin* (NPC 1999). The seven principles of good prescribing identified within this bulletin have provided a core framework for prescribers in their education and development for the past decade. However, it is important to recognise that, although these remain relevant, since their introduction, non-medical prescribing has moved forward significantly, in terms of both the range of treatments prescribable and the range of expertise and settings in which prescribing can now take place. As such, the seven principles should be seen as a four-

Table 1.1 Key principles of the Crown Report

Patient safety
Effective use of resources
Skills and competencies of various health professionals
Changes in clinical practice
Public expectations

Department of Health (1999a).

dation on which to build rather than as a measure on which to base effectiveness. The NPC (2001, 2004a, 2006), the UK health departments (DH 2006a, 2006b, DHSSPS 2006, SEHD 2006, WAG 2007, NHS Scotland 2009) and the professional bodies (HPC 2006, Nursing and Midwifery Council (NMC) 2006, RPSGB 2006) have all identified the need to develop and maintain competency in prescribing beyond qualification, developing relevant frameworks and continuing professional development (CPD) strategies. These are discussed further in Chapter 9.

Attitude shifts

The evolution and success of non-medical prescribing should not merely be measured from the context of its magnitude. It is recognised that the process has required many legal, professional and ethical changes, as discussed in Chapter 2. Fundamentally, the increase in non-medical prescriber numbers and the strategies employed to support this development have relied on a change much more difficult to measure. It would, therefore, be inappropriate to consider the context of non-medical prescribing without addressing the significant and ongoing shifts in attitude that have enabled non-medical prescribing to flourish. The processes involved in enabling legal and professional changes have often highlighted the concerns and objections of individuals and groups from both the medical profession and colleagues in other health professions. These concerns have ranged from questions of safety to issues of boundaries within professional roles (Day 2005). Importantly, the evidence base developed has addressed many of these concerns. Data from the National Patient Safety Agency (NPSA 2007) identified that, although prescribing errors still occur, most medication errors arise from administration and supply. There is no indication that non-medical prescribing activity results in an increase in prescribing errors. Interestingly, most errors reported to the NPSA (2007) occurred in the acute setting. However, data held by the professional bodies about professionals with a non-medical prescribing qualification indicate that numbers currently remain lower in secondary care than in primary care.

Many of these prescribing errors have been attributed to junior doctors but the cause of these errors has been found to be multifactorial in nature (Velo and Minuz 2009). It is unproductive to utilise the junior doctor as a diversion from the concerns raised regarding non-medical prescribing, but it does highlight issues that should provide some reassurance to those raising the concerns. Significantly, a need for specific education for all prescribers has been identified (Schachter 2009) and the content of this education suggested by Likic and Maxwell (2009) reflects that already undertaken by non-medical prescribers. It is important that this information should not be seen as a defence of non-medical prescribing, but as evidence of good practice from which others may learn.

Attitudes towards prescribing are becoming increasingly positive, with the benefits brought to specialist roles being recognised (Avery and Pringle 2005). The role of doctors has not diminished as a result of non-medical prescribing, but instead there are numerous examples of how non-medical prescribing can be used by professionals to work alongside doctors to improve the patient experience (Thomas et al 2005, Courtney and Carey 2008). The health professional case studies provide some clear examples of this issue.

It is important also to consider the attitudes of those practitioners undertaking non-medical prescribing and the impact on the team (both the immediate healthcare team and the wider organisation). Prescribing can increase a practitioner's confidence and result in greater job satisfaction but any change in role and attitude of an individual within a team can have an impact on the team dynamics as a whole (Bradley and Nolan 2007). Although this can often be a positive change in dynamics, it is important to recognise that the journey is not always straightforward and change should be supported by ensuring that the team is informed and involved.

The success of non-medical prescribing not only has required an attitude shift by professional colleagues but, possibly more importantly, also has been reliant on its acceptance by patients. A recent study investigating the views of the Scottish general public found that there was a significant awareness of non-medical prescribing (Stewart et al 2009). Interestingly, respondents from Stewart et al's (2009) study reported that they were more comfortable with pharmacist or nurse prescribing than with other non-medical groups, a finding that could, at least in part, be due to familiarity with, and experience of, the public with those professionals. The study identified that the public required reassurance regarding clinical governance issues, reiterating the need for both a strong evidence base and effective channels of communication, to ensure that the public develop an awareness of advancements in non-medical prescribing.

Non-medical prescribing, medical prescribing or prescribing

As acknowledged above, safety and efficacy have remained the key objectives for non-medical prescribing, an ethos that has been fundamental to its success. However, all health professionals would surely argue that these are essential principles that underpin their practice as a whole and, indeed, any aspect of healthcare provision. The professional and ethical codes that serve to regulate the practice of health professionals (RPSGB 2007, HPC 2008, NMC 2008a) remain as relevant to prescribing as they do to other aspects of their practice.

Therefore, the debate should perhaps focus on the need to differentiate prescribing from any other element of healthcare practice. It would be inept to fail to recognise that prescribing presents specific challenges and potential problems that require specific guidance and standards. As such, all relevant professional bodies have developed curricula and standards to ensure that education programmes prepare students to practise as non-medical prescribers within the boundaries of their professional ethical code (NPC 2004a, NMC 2006, 2009, General Pharmaceutical Council 2010).

In recognising that prescribing requires specific consideration, the relationship between non-medical prescribing and medical prescribing must be considered. It has been established that the concepts of safety and efficacy are pertinent to all healthcare practice, including medical prescribing. It is logical to consider that some practices which support safety in prescribing, such as standards for writing prescriptions (British Medical Association (BMA) and RPSGB 2010), were originally developed for medical prescribing, before the advent of non-medical prescribing.

Therefore, it is reasonable to question the necessity to even differentiate between medical and non-medical prescribing. The potential for medicines to result in harm to

patients is well acknowledged by the existence of agencies responsible for monitoring this throughout the UK (see Activity box 1.2). The data collected by these agencies reiterate the message that patient safety must be paramount, regardless of who is prescribing. The strategies, used to support patient safety and efficacy, are explored throughout the chapters of this book and adopt a holistic approach to prescribing.

This approach requires non-medical prescribers to consider all factors influencing their prescribing practice, including consultation skills, patient expectations, the clinical evidence base and CPD, in order to achieve the safest and most effective outcomes possible for the individual patient. This approach is reflected in non-medical prescribing education programmes throughout the UK. However, at present, although the objectives of medical and non-medical prescribing are fundamentally consistent, there remain stark differences in the standardisation of education with regards to prescribing between these two groups. The medical profession has shared a wealth of knowledge and skills with other health professionals as designated medical practitioners, to support them through their education and beyond. This has been invaluable in moving non-medical prescribing forward. However, it is evident that the benefits of the formalised and structured approach to providing education focused on prescribing would be relevant and valuable to all prescribers.



Activity box 1.2

The UK has dedicated agencies to address patient safety. Go to the appropriate agency website and, by accessing their resources, identify the recommendations for promoting patient safety in relation to your prescribing practice. Critically reflect on your practice and identify strengths and weaknesses in relation to patient safety:

- National Patient Safety Agency (England, Northern Ireland and Wales): www.npsa.nhs.uk
- Scottish Patient Safety Alliance: www.patientsafetyalliance.scot.nhs.uk
- Healthcare Inspectorate Wales: www.hiwi.org.uk
- Health and Social Care Safety Forum (N. Ireland): www.hscsafetyforum.com

Changes in clinical practice

One of the major drivers behind the increasing development of non-medical prescribing has been the significant changes that have taken place in clinical practice. These changes have been a direct response to the recognition of the changing health needs of the population. The DH (2007a), in its operating framework, identified priorities for

2008-9 which also evolved as a result of an ageing population. This, in turn, has resulted in an increase in the number of people with long-term conditions. In order to address the demands on services, health care must aim to reduce both hospital admissions and the subsequent lengths of stay. The priorities set by the DH (2007b) maintain the public health approach, identifying access and inequalities as target areas. In addition, the need to reduce healthcare-associated infections and to prepare for emergencies were set as priorities, while also identifying the need to improve patient experience and staff satisfaction. The workforce continues to be subject to significant changes in response to these priorities, resulting in new challenges and demands (DH 2006c, 2008b, DHSSPS 2006, SEHD 2006, WAG 2007). Implementation of current health policy involves a fundamental shift of care into the community arena (DH 2008b) with both primary and secondary care evolving in response. Non-medical prescribing has long since ceased to be a primary care phenomenon, with independent prescribing developing rapidly in the hospital setting, responding to reductions in the working hours of junior doctors and emerging new and specialist roles. The expansion of non-medical prescribing into new areas brings not only many benefits and opportunities (Goswell and Siefers 2009) but also new challenges for all those involved (Clegg et al 2006, Cooper et al 2008a, Pontin and Jones 2008).

The role of non-medical prescribing

The skills and expertise of health professionals has been recognised as a valuable resource that could be used more effectively to support development of healthcare services (DH 2000, 2002, 2006a, Scottish Government 2008a). This has resulted in the development of new roles throughout the healthcare professions, including advanced practitioners, pharmacists and allied health professionals with specialist roles, community matrons and specialist midwife roles. This, in turn, has required a redefinition of many existing roles. In response to these developments and the changes that it has elicited, it has been recognised that health professionals need further education to meet the demands of both new and existing roles (Pooler and Campbell 2006). Arguably, non-medical prescribing not only has proved useful in these developments but also in some cases has been identified as an essential component of the health professional's role, clearly indicated within the job description. In considering the vision for modern UK healthcare in providing an equitable service, which meets the needs of service users and staff, it is clear that the ability for individual practitioners to complete episodes of care is paramount. It is important to acknowledge that it would be unrealistic to suggest that prescribing, as an isolated skill, would enable practitioners to complete every episode of care. However, in the context of prescribing representing an additional skill possessed by experienced and competent practitioners, it is fair to suggest that it would enable a significant number of consultations to be successfully concluded. The principles of prescribing (NPC 1999) and subsequently the competency frameworks supporting prescribing (NPC 2001, 2004a, 2006) have reiterated the message that writing a prescription is only one aspect of the multifaceted process of prescribing practice. As such, the skills acquired by health professionals in enabling them to reach a prescribing decision, whether or not it results in the generation of a prescription, means that those consultations that require referral can proceed in a more efficient and appropriate

manner. Therefore, it is clear that, in an evolving healthcare service, non-medical prescribing is, and will continue to be, an essential component.

The economic context

The majority of prescribing activity undertaken by non-medical prescribers in the UK is undertaken by National Health Service (NHS) employees, with the cost of the treatment met by the NHS budget. The extent of spending on prescription items can be demonstrated by making reference to the document *Prescription Cost Analysis for England 2008* (NHS Information Centre for Health and Social Care 2009). In 2008, 70 million prescription items and £650 000 000 worth of payments were processed per month. The magnitude of this is compounded by the knowledge that this related only to prescriptions generated within the community.

The NHS prescribing budget, as with all areas of NHS provision, is a finite resource. As such, non-medical prescribing exists within the context of a service where resources must be used appropriately, efficiently and effectively in order that patients benefit from the full potential of the service. The consequence of this is that, in order for prescribing practice to be safe and effective, prescribers must consider issues of cost-effectiveness as part of the decision-making process. The issue of cost-effectiveness must be regarded in relation not only to the use of treatments but also to the many associate resources that complement and support prescribing practice.

The achievement of an appropriate balance between cost-effectiveness and clinical effectiveness is an aspect with which many non-medical prescribers struggle. The reasons for this are numerous, influenced by professional, legal and ethical issues. Concordance issues, patient expectations, media influences and practitioner professional development issues are just a small selection of the factors that might impact on the choice of treatment and the balance of cost-effectiveness against clinical effectiveness. Case study 1 provides an example of how local formularies have been used effectively to address some of these issues.

Local formularies and guidelines (e.g. antimicrobial guidelines) can provide clear frameworks for non-medical prescribers and are often an important consideration in aiding decision-making about treatments. However, their use has been identified by some non-medical prescribers as restrictive (Hall et al 2004). Unfortunately, the drive for cost-effectiveness can easily be mistaken by an inexperienced prescriber as a necessity to always prescribe the cheapest treatment available. It is important that local formularies are not unfairly perceived as tools to limit prescribing to the cheapest options available. An engagement with national and local medicine management processes will support the non-medical prescriber in developing an understanding of the benefits of these formularies. It is worth noting that, within individual trust policy, there is usually an option to prescribe outside the formulary (where there is a clear rationale for doing so). Maintaining knowledge and competence in relation to their specialist field, particularly in relation to national guidelines and treatment options, is essential in enabling non-medical prescribers to work effectively with local formularies, while having the expertise to challenge them when appropriate.

Activity box 1.3

Access and summarise national guidelines for a condition for which you could prescribe. Access your local formulary and guidelines and compare these to the national guidelines. Answer the following questions:

- Are there any differences?
- Is there a rationale for the differences?
- Do you know the protocol for prescribing outside your local formulary?

The private sector

Although most non-medical prescribers practise within the NHS, there are a significant and increasing number of prescribers who work within private or independent practices. Each individual practitioner is responsible for ensuring that they practise in accordance with the regulations of their professional body and, of course, this includes a requirement to practise within, and to maintain, one's own competence. This remains the case, regardless of the sector in which they are employed. In order to provide and maintain quality and standardised care, the NHS requires that nationally determined standards are adopted and implemented within individual trusts and that these in turn are implemented within individual practices. Although many private sector practices ensure that comprehensive policies and protocols are in place, others have limited and/or inadequate governance procedures in place. The DH (2006a, p. 19) recognised the potential for differences in clinical governance systems and therefore made the following statement to promote safety, regardless of the setting in which non-medical prescribing is undertaken:

... Nurse and Pharmacist Independent Prescribers who work outside NHS settings where clinical governance systems may be different or may not be applied in the same way, must ensure they comply with requirements to demonstrate their competence to practice. For example, they must be able to show how they audit their practice, keep up-to-date with current guidance, and how they safeguard the patients in their care.

One related concern has been identified in relation to injectable medicines, such as *Widex*® and *Vistabel*®, used in cosmetic procedures. The receipt of wholesale supplies of these medicines by nurses, and remote prescribing by doctors, are just two issues that have prompted the need for guidance. The Medicines and Healthcare products Regulatory Agency (MHRA 2008) provided clear direction which also incorporated the position of the NMC in relation to nurses, based on *The Code: Standards of conduct, performance and ethics for nurses and midwives* (NMC 2008a) and *Standards for medicines management* (NMC 2008b). In undertaking a non-medical prescribing programme, health professionals are required to analyse their practice and become aware

of their responsibility and accountability. This can be seen only as a positive outcome that will support safe and effective practice. The NMC (2007) acknowledged that some nurses were also moving into this area of practice after completion of a non-medical prescribing programme which prompted the identification of additional content for programmes to ensure that issues relevant to this area of practice are addressed.

The public health context

Public health was determined as a core theme of this book, due to its significance in modern UK healthcare. Addressing public health issues was clearly intended to be one of the key functions of non-medical prescribing, with health promotion being identified as one of the four original areas suitable for prescribing from the extended formulary (DH 1998). Although this categorisation has long ceased to be used, the need to consider health promotion and public health in non-medical prescribing practice remains essential.

UK public health policy

Current UK public health policy incorporates strategies to meet targets rather than simply addressing specific diseases and significantly focuses on tackling inequalities. This is due in part to the recognition that poverty and its associated health inequalities originally identified in the Black Report (Black et al 1980) and reiterated by Acheson (1998) and Wanless (2004) remain a key factor in the health of the population. As such, tackling health determinants has consistently been identified as an essential concept in UK health policy (DH 1999b, 2004, Scottish Government 2008b). The health agenda described by DH (2004) identified long-term key target areas (Table 1.2) with the objective of supporting and empowering the public to make healthier and informed choices.

This approach is reflected in the definition of public health provided by Acheson (1998):

Table 1.2 Choosing health key target areas

Accidents
Alcohol
Diet and nutrition
Inequalities
Mental health
Physical activity
Sexual health
Substance misuse
Tobacco

Source: Department of Health (2004).

The science and art of preventing disease, prolonging life and promoting health through the organised efforts of society ...

It is significant that this definition recognises the organised, multiagency partnership approach necessary for tackling health determinants. This reflects the messages in Chapter 6, supporting the need for a team approach to prescribing, in order that safety and efficacy are maximised. Acheson (1998) and Wanless (2004) stress that we all have a responsibility for our public health. This responsibility is both personal and professional, as individuals with responsibility for our own health (DH 2004) and as health professionals with responsibility to provide services that support public health (DH 2002).

It has been argued that every prescribing situation has a potential opportunity to promote health and address public health issues, but relies on individual practitioners developing an awareness of the current health issues, national and local targets, and factors determining health. Furthermore, it requires non-medical prescribers to recognise and embrace the opportunities to impact on public health targets elicited within the prescribing situation (Nuttall 2008).

Need and expectations

The public health focus of modern health care requires that the needs of the population are clearly identified and met. Bradshaw's *Taxonomy of Needs* (Bradshaw 1972, cited in Bradshaw 1994) considers categories of need that, although rudimentary, provide a useful framework for consideration. In relating this categorisation to both the health needs of the UK population and non-medical prescribing practice, links to policy development, health provision and, indeed, public expectation can be clearly identified. The first category of 'felt need' relates to issues or factors that members of the population feel constitute a need. These needs are felt but not articulated. Once these needs are articulated, they fall in to the second category of Bradshaw's taxonomy: 'expressed need'. The third category of 'normative needs' refers to issues and factors that health professionals have identified as needs within the population. These needs are usually based on epidemiological data and population profiles that identify key health issues in the population as a whole but also in specific communities within the wider population. The final category of 'comparative need' refers to the needs that are determined by making comparisons between individuals within the same community or population. In a health service where the philosophy is to ensure that the patient and his or her individual needs are placed at the centre of the care provided (DH 2006c), it is essential that all these needs be considered.

Current national health targets are largely based on normative needs, which are targeted more specifically at local level. However, although normative needs are generally an accurate representation of broad health needs, they can often differ from those felt and expressed by users of the health service. The disparity may in part be due to differences in prioritisation between service users and service providers. To ensure that non-medical prescribing is meeting the needs of the population, it must not only target public health issues previously identified but also ensure that patients and carers have the ability to express their felt needs.

The DH commissioned a study by the University of Southampton in 2005, to evaluate extended formulary independent nurse prescribing. This study did seek the views of patients, as well as those of nurses and doctors. However, the number of patients involved was unclear and the summary of their responses was broad. The DH has commissioned a further study with Southampton and Keele Universities (Keele University 2009), which will evaluate nurse and pharmacist independent prescribing. This again has an element of patient focus, though it is still unclear if this will enable patients to express their needs. It remains essential to ensure that subsequent research and consultation seeks the views of service users as well as those governing or providing the service.

On an individual level, non-medical prescribers have a responsibility to ensure that the processes and strategies used with individuals enable the patient and carers to receive a service that meets their needs. This may be achieved through a number of measures, not least through the strategy fundamental to safe and effective prescribing - that of the holistic assessment. Concordance, which is discussed in depth in Chapter 5, relies on negotiation between the patient and the non-medical prescriber. For any negotiation to be effective, it must take in to account the needs and views of the individuals involved and there is an expectation that these needs will be adequately considered.



Activity box 1.4

Take time to reflect on your practice and consider the following questions:

- Do you allow patients to express their needs?
- Are there any barriers to this?
- What strategies could you employ to improve the ability of patients to express their needs?

Differentiating between prescribers

The first part of this chapter explored the wider context of prescribing in the UK. However, it is important to identify how individual practitioners apply non-medical prescribing within the context previously examined. The terms 'independent' and 'supplementary' used in relation to prescribing cover a range of professions and a range of prescribing activity. Therefore, the latter part of this chapter differentiates between independent prescribing and supplementary prescribing. It also explores the application of both types of prescribing within the practice of different health professionals.

Independent prescribing

The term 'independent prescribing' has been (and still is) used in a variety of contexts, all presenting differences in its meaning and application. This may cause confusion to

those new to the concept of non-medical prescribing, not least because of the use of the term both as a title identifying prescribing activity by a particular type of prescriber and as a method of prescribing in itself. It is important to clarify these issues, recognising that independent prescribing is a core concept that underpins prescribing practice by many professional groups.

Independent prescribing was identified as one of two types of prescribing recommended in the final report of the *Review of Prescribing, Supply and Administration of Medicines* (DH 1999a). It was originally anticipated that independent prescribing would address undiagnosed conditions. However, the current working definition has evolved beyond this.

Independent prescribing is defined by the Department of Health (2006b, p. 2) as:

... prescribing by a practitioner responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing ...

This definition is clearly underpinned by legal, professional and ethical principles, with responsibility and accountability at its centre. It identifies a method of prescribing where the individual professional undertaking prescribing practice must be able to make a prescribing decision and support this with a clear rationale. This, of course, reflects professional practice requirements, while recognising the specific factors supporting safe and effective prescribing. The DH (2006b) definition is significant in that it recognises three important factors in relation to independent prescribing:

1. Assessment is fundamental to safe and effective prescribing.
2. Practitioners who prescribe independently may do so for undiagnosed and/or diagnosed conditions.
3. Independent prescribing involves making a decision about clinical management, which may or may not require a prescription to be generated.

Assessment

A deeper exploration of these factors highlights fundamental practice issues that are frequently identified by both training and practising prescribers. The key elements of assessment are considered in depth in Chapter 4 of this book, with the link to safe and effective prescribing clearly identified. Indeed, independent prescribing requires that assessment is a key component of the process, with the prescriber responsible and accountable for this. Essentially, independent prescribing is a process that relies on the information gleaned from an assessment in order that a diagnosis and/or clinical management decision can be reached. In most instances, the assessment will be an integral element of the consultation process. However, this raises the question of whether or not the prescriber must undertake the assessment.

One of the issues highlighted by *Saving Lives: Our healthier nation* (DH 1999b) was that nurses were undertaking assessments and making decisions about clinical management of patients' conditions. Doctors were then issuing prescriptions based on the judgement of these nurses. Not only did this highlight the often unrecognised knowledge

and expertise of many nurses, but it also identified safety issues in relation to these practices. One of the main advantages of non-medical prescribing was therefore that it enabled the same practitioner who had undertaken the assessment, and who was in possession of all the relevant information, to prescribe treatment if necessary. However, some practitioners will argue that this is not always possible or indeed necessary. This again raises further issues, which often relate not only to the individual prescriber's practice but also to the expectations of colleagues.

Ultimately, the independent prescriber is responsible and accountable for the assessment of the patients for whom he or she will make a decision about clinical management. There may be an expectation by some health professionals that their prescribing colleague will issue prescriptions on their request. Of course, in some instances, non-medical prescribers may work alongside colleagues who are competent in assessment and diagnosis of specific conditions, and in whose ability they are very confident. However, the NMC (2008b) has considered the issue of remote prescribing, and has determined that it is only acceptable in exceptional circumstances. Practice issues such as these often highlight other areas that need to be addressed. Although many health professionals may be competent in assessment in order to reach a diagnosis, it is possible that their assessment does not address all issues relevant to making a safe prescribing decision. Furthermore, if these practitioners are competent, there is an expectation that they should be identifying, within their own practice, the need to prescribe themselves, and as such should endeavour to undertake the appropriate programme of education.

Diagnosed and undiagnosed conditions

The Department of Health's (2006a) definition of independent prescribing significantly included diagnosed conditions within its remit, an element missing from previous definitions. This change recognised the fact that non-medical prescribers who prescribed independently may do so in a variety of situations, treating a wide range of patients and conditions. As such, some non-medical prescribers will treat only patients who have been previously diagnosed, whereas others would be making the initial diagnosis and prescribing for that condition. Many non-medical prescribers will prescribe for both previously diagnosed and undiagnosed conditions. As practitioners preparing to undertake a non-medical prescribing education programme, individuals will have a clear indication into which category they fall. However, in reality, the boundaries are arguably more difficult to define, e.g. the practitioner whose case load includes only patients who have previously been diagnosed may find that they present with side effects of treatments that may require short-term treatment. Equally, patients may also present with an unrelated complaint for which the non-medical prescriber is still competent to prescribe.

The prescribing decision

In considering the context of independent prescribing, it is important to reiterate the message set in the prescribing principles (NPC 1999), reinforced in the competency frameworks (NPC 2001, 2004a, 2006), and embedded in the Department of Health's (2006a) definition, that prescribing a drug is only one option available to the practitioner prescribing independently. Indeed, it would be inappropriate to prescribe a drug

without providing some health promotion, whether that be advice on physical measures to be taken to support the drug treatment, e.g. dietary advice when prescribing statins, or preventing accidents such as overdose by giving clear instructions for taking the drug. Strategies used to reach a prescribing decision are discussed at length in Chapter 4 but the key message is that it is not a requirement that independent prescribing results in a prescription. The processes and strategies used will vary, and an appropriate prescribing decision to be made which may mean that only health promotion advice is necessary or that referral is needed, either in isolation or in support of a drug treatment. The practitioner trained as an independent prescriber will have developed skills that reach far beyond simply being able to write a prescription. The decision to prescribe or not will be made within the context of a holistic and multidisciplinary approach to consultation and treatment options.

Who are independent prescribers?

The process of independent prescribing requires appropriate professionals to undertake the activity. Non-medical prescribers hold a recognised qualification, which is annotated on the relevant professional register, and continue to demonstrate competence in assessment, diagnosis, decision-making and treatment of specific conditions (DH 2006a). The conditions for which they prescribe may be limited to one or may be wide ranging. These professionals are referred to as *independent prescribers*. Unfortunately, the terminology does not lend itself to a simplistic interpretation of the role. Not only is the term 'independent prescriber' used to describe the professional undertaking independent prescribing but it is also a title given to specific prescribers, recorded as such by their professional bodies. This, in essence, means that although a range of professionals undertake the processes highlighted within the DH (2006a) definition, and as such undertake independent prescribing, they would not necessarily be referred to as independent prescribers. Supplementary prescribing is more distinct and it is anticipated that understanding the differences between supplementary and independent prescribing will provide further clarity when considering the role of prescribers within individual professional groups.

Activity box 1.5

Look at case study 1 at the back of this book and consider the following questions:

- Is non-medical independent prescribing the appropriate method for this patient to access medicines?
- What is your rationale for your answer?
- Would there be any potential barriers to you undertaking non-medical independent prescribing for this particular patient?

Supplementary prescribing

Supplementary prescribing, in common with independent prescribing, has evolved from the recommendations made in the final report of the *Review of Prescribing, Supply and Administration of Medicines* (DH 1999a). The original reference was to 'dependent prescribing' where a dependent prescriber would be responsible for the continuing care of patients who had initially been assessed by an independent prescriber. Although the terminology and, indeed, the definition have altered, the core principles have remained very much the same. The current definition of supplementary prescribing is:

... a voluntary partnership between an independent prescriber (a doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific clinical management plan (CMP) with the patient's agreement ...

DH (2005, p. 8)

Undertaking supplementary prescribing therefore requires application of the key principles underpinning it. One key principle of supplementary prescribing is that of partnership. The dynamics of supplementary prescribing are different to those of independent prescribing in that the non-medical prescriber takes on the role of supplementary prescriber, with a doctor (or dentist) adopting the role as independent prescriber. This means that the doctor (or dentist) takes responsibility for a diagnosis, or a decision relating to the review of an existing diagnosis, at the time of the development of a CMP. The supplementary prescriber is then able to review the patient and manage the longer-term care of the patient. This crude interpretation is not a complete reflection of supplementary prescribing because it understates the partnership context that is crucial to its success.

The role of partnership

Partnership in supplementary prescribing is essential in order to effectively achieve the following fundamental requirements of supplementary prescribing:

- Agreement on which patients will be suitable for supplementary prescribing
- Obtaining the patient's agreement to being treated under a CMP
- Agreement of an individual CMP
- Maintenance of communication in relation to review and prescribing.

However, the necessity for partnership extends beyond this. In addition to the responsibility for the diagnosis, the independent prescriber is responsible for the boundaries of the CMP (DH 2005). To effectively set boundaries within which the supplementary prescriber will prescribe, it is crucial that there is an honest exchange to determine the competence of the supplementary prescriber and to ensure that the expectations of the independent prescriber remain within the parameters of that competence. Furthermore, the independent prescriber has a responsibility to provide support and advice to the supplementary prescriber as required (DH 2005). Arguably, this relies in part on the confidence of the supplementary prescriber's ability to seek and receive this support as necessary. Equally, the independent prescriber will have expectations

that the supplementary prescriber accepts responsibility, and is accountable, for his or her own prescribing practice (see Chapter 2).

The concept of partnership in supplementary prescribing extends beyond the relationship between the independent prescriber and the supplementary prescriber. In actual fact, the whole concept of supplementary prescribing relies on a three-way partnership, with the patient completing the tripartite collaboration. The patient must be aware of, and agree to, the intention to facilitate his or her care through a CMP, and his or her agreement to receive care via supplementary prescribing must be documented (DH 2005).

The clinical management plan

As already stated the CMP is an essential component of supplementary prescribing and as such must be drawn up before prescribing begins. The CMP may be hand-written or completed electronically but must be relevant to the specific patient and his or her specific condition(s) (DH 2005). Table 1.3 identifies the information that the Department of Health (2007c) determines must be included within a CMP and an example of a completed CMP can be seen in case study 9.

So that supplementary prescribing is utilised efficiently and safely, CMPs need to be relatively quick and simple to complete (NPC 2007). However, there is often confusion about their completion and this has contributed to the notion that their development takes too long to complete. Although the information that must be included may seem extensive at first glance, there are acceptable methods of reducing the magnitude of the information on the CMP, provided that the full details are easily accessible, e.g. as detailed in Table 1.3, it is not necessary to list every medication and every possible condition on the CMP if it directly reflects that stated in a recognised published guideline. Instead, it is perfectly acceptable to indicate that treatment will be given in line with the guidelines (identifying specific sections where appropriate) named on the CMP, provided that they are readily available to both the independent prescriber and the supplementary prescriber. Similarly, detailed patient information, available to both pre-

Table 1.3 Essential information to be included on a clinical management plan (CMP)

Patient's name
Condition(s) for which the supplementary prescriber may prescribe
Start date for CMP
Date for review by the independent prescriber
Identification of medicines or appliances that may be prescribed under the CMP ^a
Identification of limitations or restrictions of identified medicines, including strength, dose, period of use ^a
Indications for referral back to the independent prescriber
Allergies, sensitivities and difficulties relating to medicines or appliances
Arrangements for notification of adverse reactions and incidents of potential or actual serious harm from appliances

^aReference to relevant parts of published guidelines may be made instead provided that they clearly identify the required information and are easily accessible. Department of Health (2007c).

scribers in shared records, does not need to be recorded on the CMP unless there is a specific need to do so.

In addition to the information necessary on a CMP, there is a need for clarity about responsibility for its completion and the signatures required. Although the CMP must be agreed by both prescribers, either may take responsibility for composing it. A CMP that contains the signatures of both the independent and supplementary prescribers provides clear evidence that it has been agreed and, therefore, could be considered preferential. However, it is not always possible for the CMP to be signed by both prescribers and, as such, it is not an essential requirement. However, agreement to the CMP must be recorded in the patient's record (DH 2005). Similarly, although the patient's agreement must be obtained if he or she is to be cared for using a CMP, it is not necessary for the patient to sign it. However, a record that a discussion has taken place, and that the patient has agreed, must be recorded in the patient's records (DH 2005).

A further consideration in relation to CMP use is the potential for more than one supplementary prescriber to be involved in the patient's care. If more than one health professional, who is able to prescribe as a supplementary prescriber, is involved in the care of the patient in direct relation to the condition(s) indicated on the CMP, then he or she is able to prescribe from it, provided that (DH 2005):

- they agree to the CMP
- they are named on the CMP
- they have agreed strategies of communication between all prescribers
- they have access to consult and use the same part of the common record.

Termination of supplementary prescribing

Partnership working and agreement are fundamental throughout the process of supplementary prescribing and this extends to the point at which a CMP may be terminated. As supplementary prescribing relies on the three-way agreement previously discussed, the CMP must be terminated in the event of any circumstances that compromise this partnership (Table 1.4). The Department of Health (2005) determines that an existing CMP could be used by a replacement supplementary prescriber, provided that he or she agreed to the CMP and was then named on it.

The initial development of a CMP requires an agreement to be made about a date for a joint formal review. This should generally be within a maximum of 12 months unless the stability of the patient's condition indicates otherwise (DH 2005). Essentially, the date of review must be appropriate to the needs of the patient and his or her presenting

Table 1.4 Circumstances for termination of the clinical management plan

At the request of the independent prescriber (IP), the supplementary prescriber (SP) or the patient
If the named SP is unable to continue in this role and is the only named SP
At the set review date (unless agreement has been made to continue)

Department of Health (2005).

conditions). The CMP will be terminated at the set review date unless it is agreed at the review that the CMP is to continue.

Who are supplementary prescribers?

Supplementary prescribing was enabled by changes in legislation in 2003. These changes allowed first level registered nurses, registered midwives and registered pharmacists to undertake supplementary prescribing, following a recognised programme of education. Subsequently, in 2005, further changes in legislation enabled defined professions from the allied health professions to undertake supplementary prescribing. The allied health professionals were radiographers, podiatrists, physiotherapists and optometrists. A recent scoping and analysis of services has recommended the expansion of supplementary prescribing to other allied health professions and to enable physiotherapists and podiatrists to prescribe independently (DH 2009). Legislative changes will be required to enable these developments. For detailed explanation of the law in relation to non-medical prescribing, see Chapter 2.

Resistance to supplementary prescribing

The introduction of supplementary prescribing brought with it the expectation that its use would be in the management of long-term conditions, with the inclusion in some instances of acute episodes within these long-term conditions (DH 2005). Indeed, there is much evidence of its usefulness in this area of healthcare (Carey and Courtney 2008). Although having distinct characteristics, the aim of supplementary prescribing reflects the ethos of non-medical prescribing as a whole, in that its intention is to use the skills of health professionals more effectively and enable patients to access medicines more affordably (DH 2005). The benefits of supplementary prescribing were arguably much greater at its inception when independent prescribing was limited to a formulary. Supplementary prescribing enabled health professionals to prescribe drugs within the parameters of a clinical management plan, who, although competent to do so, were largely unable to prescribe as an independent prescriber. The evolution of independent prescribing has eliminated this as a rationale for supplementary prescribing. Many qualified, and even training, non-medical prescribers would argue that, as they would only prescribe for conditions for which they are competent to do so, they would be competent to prescribe for these same conditions independently. However, in many ways, this has clouded the benefits of supplementary prescribing which always extended beyond simply enabling a broader range of medicines to be prescribed.

In attempting to highlight the continued benefits of supplementary prescribing, it is useful to deconstruct the actual and perceived purposes of its introduction. Supplementary prescribing was introduced to treat long-term conditions. This aspect remains unchanged because it would rarely be an efficient use of resources to develop a CMP for a condition that would respond to a short-term, and often simple, programme of treatment. However, the argument remains that, even in the care of long-term conditions, non-medical prescribers are able to make independent prescribing decisions. It is perhaps this argument that has had the greatest impact on the perceived usefulness of the CMP. Yet, it could be argued that, in making the case for independent prescribing in long-term conditions, there is an assumption that all patients are relatively typical, that the progress of the condition is predictable and that the response to treatment is

generally straightforward. Furthermore, it also suggests that all non-medical prescribers would be confident and competent to treat any patient provided that they presented with a condition for which they were competent to prescribe. When presented in this manner, the argument seems more fluid.

Realistically, many new non-medical prescribers find the prospect of prescribing very daunting. It is recognised that, for some practitioners, supplementary prescribing is a useful method of allowing them to develop their skills in prescribing and, in turn, increase their confidence (DH 2005). Of course, some patients have a simple medical history and respond well to the routine treatments indicated for their long-term condition. However, many others are much more complex, with multiple medical conditions and/or polypharmacy issues that increase the likelihood of complications. In such instances, the supplementary prescriber may feel that the ability to discuss the patient's needs and to determine a suitable plan of management within predetermined boundaries, enables him or her to prescribe more safely and, indeed, more confidently.

Although pharmacists, nurses and midwives are able to prescribe independently, at present allied health professionals are able to prescribe only as supplementary prescribers, thus requiring a CMP to be in place for any patient for whom they would want to prescribe. As is recognised in nursing and pharmacist practice, supplementary prescribing is not appropriate for every patient, requiring the allied health professionals in some instances to refer to an independent prescriber instead. These limitations do not serve to improve the profile of supplementary prescribing by being the only tool available to prescribe. However, they do successfully demonstrate that supplementary prescribing is a useful method of prescribing for some patients but that other methods need to be available to meet the needs of the client/patient group as a whole.

Considering the current UK context of non-medical prescribing, there are limitations that serve to maintain the need for supplementary prescribing. Pharmacists, for example, are unable to prescribe any controlled drugs as an independent prescriber and nurses and midwives are able to prescribe only a limited range of controlled drugs for specific conditions (note that community practitioner nurse prescribers cannot prescribe any controlled drugs). In instances where controlled drugs are necessary, the CMP enables the non-medical prescriber to meet the patient's needs. It is anticipated, however, that, even without any legal limitations relating to controlled drugs, some non-medical prescribers would choose to use supplementary prescribing as a safety mechanism.

The development of supplementary prescribing and clinical management plans has been hindered by medical apathy and implementation problems (Cooper et al 2008b). Indeed, it has been perceived as a time-consuming process, an issue that for some outweighs any benefits of supplementary prescribing. CMPs do involve an initial outlay of time in their development but, when used appropriately, this is reimbursed through the time saved by enabling the supplementary prescriber to undertake subsequent reviews. Although CMPs must be relevant to individual patients, it is acceptable for prescribers to develop CMPs for specific conditions provided that they are refined for each patient in order to meet their individual needs.

Difficulties in accessing records have also proved problematic for some non-medical prescribers. DH (2005, p. 19) stated that in supplementary prescribing:

The independent prescriber and the supplementary prescriber must share access to, consult, keep up to date and use the same common patient record ...

This has often been misinterpreted to mean that only supplementary prescribers who use the same patient records as the independent prescriber can undertake prescribing. This would eliminate a large number of non-medical prescribers, particularly those who work in areas with limited direct medical input. The requirements in relation to records is that there must be a common record where prescribing is documented. The mechanism for enabling this must be agreed by the independent prescriber and the supplementary prescriber, so that both prescribers remain aware of the current status of the treatment plan.

A further challenge experienced by practitioners in relation to supplementary prescribing is that of responsibility of diagnosis. Podiatrists, for example, often see patients who have been referred to them by a doctor, in order that they, as the specialist, make a diagnosis and often a decision about treatment. Although this obviously supports the need for independent prescribing for these professional groups, it should not be seen as a barrier to supplementary prescribing. In fact, developing supplementary prescribing partnerships within these circumstances enables effective use of specialist knowledge and skills in a shared decision-making context.

Although it is important to recognise the limitations of supplementary prescribing in an evolving context of non-medical prescribing, it is equally important not to lose sight of the many benefits that remain. To promote an understanding of these benefits, it is pertinent to provide clear examples of when it might be utilised effectively.

Activity box 1.6

Look at case study 9 at the back of this book and consider the following questions:

- Is non-medical supplementary prescribing the appropriate method for this patient to access medicines?
- What is your rationale for your answer?
- Would there be any potential barriers to you undertaking non-medical supplementary prescribing for this particular patient?

Nurse non-medical prescribers

The NMC currently validates courses to train three different types of non-medical prescriber (NMO, V150 and V300), all of whom have fundamental similarities, yet some distinct differences.

V100 non-medical prescribers

The history of non-medical prescribing identified that health visitors and district nurses were the first groups of professionals to undertake non-medical prescribing. This prescribing was, and still is, limited to a defined formulary. This limited formulary is known as the Community Practitioner Nurse Prescriber Formulary and contains items felt to be relevant to community practitioner practice. Although some prescribers have found the formulary to be limiting (Hall et al 2004), the extent of prescribing undertaken from this formulary and the limited number of health visitors and district nurses who go on to extend their prescribing role would suggest that, in the main, this is an appropriate formulary. However, V100 or community practitioner nurse prescribing is an extended role available to all community practitioners, including school nurses, community mental health nurses, community children's nurses and general practice nurses, provided that they have undertaken and successfully completed a specialist community practitioner programme. The V100 education programme is incorporated into many specialist community public health nursing and community specialist practice programmes as a core component, although the requirement for specific groups within these programmes to undertake the V100 element varies. However, when V100 is not a compulsory element, dictated by either programme specification or local trust requirements, few of these other nursing groups have chosen to undertake V100 prescribing education. The limitations of the formulary are no doubt a significant reason for this apparent lack of interest in prescribing, with its contents still very much relevant to health visitors and district nurses. However, there are also other possible explanations that must be recognised.

Competence is a crucial element in nursing practice and one that is equally important in prescribing. Interestingly, although some practitioners would consider themselves competent to make a decision about a need for treatment with many drugs within the *British National Formulary* (BNF), they would not do so in relation to the drugs within the community practitioner nurse prescribing formulary. For example, a community mental health nurse may assess the patient, decide that an increase of his selective serotonin reuptake inhibitor (SSRI) is necessary and prescribe the treatment (if appropriately trained) from the BNF. However, the same nurse may not feel competent to make a diagnosis of constipation and so would not prescribe, even though there are drugs available to treat constipation within the community practitioner nurse prescriber formulary. Other legal and ethical issues may also impact on the decision by some specialist community practitioners not to undertake the V100 education programme. Consent is often problematic, for example, for school nurses. Although they may feel that, with further education, they would be competent to prescribe from the formulary, they may argue that the legal and ethical constraints of prescribing for children within the school environment would make it impossible. However, it is worth noting that changing roles for school nurses mean that there is potential to prescribe in other settings where the issues are different from those within the school. Day (2007) identified clear benefits of non-medical prescribing within a school nursing role. However, this was limited to a specific setting and supported V300 prescribing rather than V100.

V100 prescribing requires the nurse to make an assessment, diagnose or review an established diagnosis, and decide on the appropriate treatment (which may include

prescribing). As such, V100 prescribing can be seen to be representative of independent prescribing. Case study A provides an example of V100 prescribing in practice.

V150 non-medical prescribing

Initially community practitioner nurse prescribing has become well established since it was introduced throughout the UK and, overall, has confirmed the benefits suggested at its introduction. However, the service provided by community nurses has evolved and, as such, the adequacy of V100 prescribing to meet current service needs has been in question. Indeed, it has become evident that, in many areas, developments in community nursing have, unintentionally, had an adverse impact on prescribing. This impact has included limitations on practice caused by the lack of available non-medical prescribers and, as a result, has also often supported poor prescribing practice. Changing roles in district nursing has meant that many experienced nurses have moved to newly developed roles, and teams that once had a number of nurses with a community specialist or public health qualification now often have only one. These nurses are responsible for leading a team of staff nurses who generally do not hold the V100 qualification and so are unable to prescribe. The obvious impact of this change is a significant reduction in the number of non-medical prescribers within district nursing teams. This, in turn, has meant that, overall, fewer episodes of care can be completed by district nurses. The consequence of this is that alternative strategies have been employed to address the need for numbers of available prescribers within a service that has maintained a need for non-medical prescribers. Although no doubt well intentioned, these strategies have often involved practice that does not conform to the standards supporting safe and effective prescribing. In effect, practices that V100 prescribing aimed to replace have now re-emerged in a new guise.

In recognition of these problems, and of the obvious need for more prescribers, a study of the education needs of community nurses was undertaken by Fitzpatrick et al (2003). The findings from their work led to the introduction of V150 community practitioner nurse prescribing. The V150 prescriber is able to prescribe from the same formulary as the V100 prescriber, but undertakes the education programme as a stand-alone module of study rather than as part of a community specialist practitioner or specialist community public health nursing programme. The differences in context of the education programmes for V150 and V100 have determined the differences in the content of the courses. The V150 education programme incorporates additional study days which are primarily to consider leadership and related issues that V100 students receive within the wider specialist nursing programme. The requirement for the nurse to assess the patient, reach a decision about diagnosis or outcome of a review, and negotiate treatment means that, as with V100, V150 prescribing can be seen to be representative of independent prescribing.

The introduction of V150 prescribing varies dramatically throughout the UK. The north west of England has already trained significant numbers of nurses and numbers are steadily increasing in other areas of England. V150 education programmes are becoming available in other areas of the UK, subject to the identification of a service need. King and Schallowok (2009) recognise that V150 can be a useful tool in meeting the needs of services where there is a need for more prescribers but where V300

prescribing is not indicated. Case study C provides an example of how V150 prescribing has improved services for patients.

V300 independent/supplementary nurse prescribers

Nurses and midwives who wish to undertake education to prepare them to prescribe as independent prescribers will now access programmes that incorporate both independent and supplementary prescribing. It is worth clarifying at this juncture that V200 extended formulary nurse prescribers were trained as independent prescribers but were able only to prescribe from a specific formulary known as the 'extended formulary'. This has now been replaced by the V300 programme. V200 prescribers are no longer limited to this formulary but may or may not have accessed further education in supplementary prescribing. Supplementary prescribing is considered in detail later.

As with all the aforementioned types of nurse prescribers, V300 independent prescribing incorporates all the elements of independent prescribing previously determined but allows a much more extensive range of medicines to be prescribed. Unlike V100 and V150 prescribers, who are limited to the community practitioner formulary, V300 prescribers can prescribe any drug (including some controlled drugs), for any condition. However, despite the differences in the range of medicines available to the V100, V150 and V300 prescribers, there remains a common restriction that limits the range of medicines actually prescribed. That restriction is enforced by the NMC in its standards for prescribing, which reinforce the need for individual practitioners to prescribe only within the limits of their competence. Furthermore, restrictions may be set locally to address concerns relating to specific areas of practice, e.g. a study conducted in Wales by Jones (2008) identified a view among health professionals that a cautious approach was needed in the implementation of independent prescribing in mental health settings. Studies in both Scotland (Snowden 2008) and Ireland (Wells et al 2009) reflected this, albeit within differing contexts.

The term 'independent prescribing' has been used consistently in relation to V300 prescribing for many years. As a result of this, many people would use the terms 'V300' and 'independent prescriber' synonymously. However, as previous discussion identified, supplementary prescribing is a key strategy in V300 prescribing, the benefits of which are commonly overlooked.

Although it is intended that, when using the term 'nursing' within this book, reference is also being made to midwifery and health visiting, it is important to recognise that the uptake and prescribing needs of these specific professions do not necessarily match those of the wider nursing profession. Non-medical prescribing qualifications recorded by the NMC show that access to V300 education programmes by both midwives and health visitors has been significantly lower than for other nursing professions. The reasons for this vary but may include both service need and benefit-awareness issues. Many health visitors may argue that, although the community practitioners' formulary does not enable them to prescribe everything that they require, the service need does not warrant them undertaking the V300 education programme. However, some health visitors do have specialist skills that would be better used if they were able to prescribe a wider range of medicines. Case study A at the end of the book provides an example

of how V300 prescribing can improve the service offered by health professionals and make best use of their skills.

Similarly, midwives have specific exemptions in medicines legislation, which enables them to supply and administer specific medicines in specified circumstances (NHS Education for Scotland 2006, MHRA 2007). Many midwives would suggest that this supports the need for undertaking non-medical prescribing. However, many of the exemptions relate to the period around labour and the childbirth situation, and do not cover many of the situations encountered in the postnatal period in the home. Case study B provides an example of the application of V300 prescribing in midwifery practice.

Activity box 1.7

Consider the following examples of nursing practice. Decide which type (V100, V150, V300) of prescribing would be most appropriate:

1. A nurse on a rehabilitation ward. She currently has to wait for a doctor to prescribe medicines for conditions that she is competent to treat.

2. A community staff nurse who has undertaken extensive training in wound care in order to change a treatment, he has to request a prescription from the GP or ask his team leader to review the patient.

3. A health visitor. He trained 15 years ago but gave up work for 5 years to care for his child. He completed a return to practice course 3 years ago. He is now only health visitor in his team without a prescribing qualification.

Pharmacist non-medical prescribers

As a result of the response to the legislative restrictions and subsequent changes, has associated programmes of study to train pharmacists as supplementary prescribers and independent and supplementary prescribers, and to enable those trained as supplementary prescribers to become independent prescribers.

Pharmacist supplementary prescribers

Pharmacists who undertook a programme of education in non-medical prescribing before the legislative changes of 2008 were able to train and subsequently practise as supplementary prescribers. This enabled pharmacists to prescribe any medicine identified within a CMP under the criteria of supplementary prescribing discussed earlier. Pharmacist supplementary prescribers do not have any restrictions on the drugs that they may prescribe or on the conditions for which they may prescribe. This enables pharmacists to prescribe controlled drugs and unlicensed drugs where there is a patient need and has been agreed by the independent prescriber and the supplementary prescriber within the CMP.

Some pharmacist supplementary prescribers have found that supplementary prescribing has improved patient management and their role within it (Johnson et al 2006). However, many pharmacist supplementary prescribers have identified that the ability to prescribe independently would enhance their role further by enabling them to prescribe in situations where supplementary prescribing is inappropriate. These pharmacists have undertaken additional education on conversion courses that focus on the elements particularly significant in achieving safe and effective independent prescribing. Pharmacists undertaking courses validated to encompass the 2008 legislative changes will receive education in supplementary prescribing as part of the independent prescribing programme. It is important again to reiterate the advantages of supplementary prescribing as previously highlighted. The perceived superiority of independent prescribing can detract from the benefits of pharmacist supplementary prescribing (Cooper et al 2008). Case study D provides an example of pharmacist supplementary prescribing.

Pharmacist independent prescribers

Pharmacist independent prescribing incorporates all the elements of independent prescribing previously identified. Pharmacists who have successfully completed a recognised programme of education will be able to prescribe any licensed or unlicensed medicine within their clinical competence. However, independent prescribing for pharmacists has not eliminated the need for supplementary prescribing, nor has it enabled them to prescribe all medicines that they may feel competent to prescribe. Pharmacist independent prescribers are not able to prescribe controlled drugs. Case studies E and F provide examples of pharmacist independent prescribing.



Activity box 1.8

Consider the following examples of pharmacist practice. Decide which type (independent or supplementary) of prescribing would be most appropriate:

Beth is a community-based pharmacist who reviews patients in a busy GP practice. She sees patients already diagnosed with hypertension and advises on any necessary changes in medication.

William is a hospital-based pharmacist who works in a specialist drug dependency unit. He reviews patients on a methadone programme.

George is a pharmacist specialising in heart failure. He reviews a range of patients who are receiving medicines to treat chronic cardiac failure.

Allied health professional non-medical prescribers

The HPC, in response to the legislative changes in 2005, has validated courses to train eligible allied health professionals as supplementary prescribers. However, this is

currently available only to physiotherapists, radiographers, podiatrists/chiropractors and osteopaths. As optometrist training includes specific requirements not indicated for most allied health professions, they are considered separately.

Physiotherapist, radiographer and podiatrists/chiropractors supplementary prescribers

Allied health professionals are able currently only to train and prescribe as supplementary prescribers. This enables physiotherapists, radiographers and podiatrists/chiropractors, in line with other supplementary prescribers, to prescribe any medicine identified within a CMP under the criteria of supplementary prescribing discussed earlier. Allied health profession supplementary prescribers also have no restrictions on the drugs they may prescribe or on the conditions for which they may prescribe. This enables physiotherapists, radiographers and podiatrists/chiropractors to prescribe controlled drugs and unlicensed drugs where there is a patient need and where it has been agreed by the independent prescriber and the supplementary prescriber in a CMP (DH 2006b).

The HPC (2008), in line with the NMC (2008a) and RPSGB (2007) have encompassed all methods of prescribing in their ethical and professional codes. This ensures that physiotherapists, radiographers and podiatrists/chiropractors restrict their prescribing practice to those conditions for which they are competent to prescribe.

As identified in pharmacist prescribing, supplementary prescribing does not meet the needs of all allied health professional non-medical prescribers. Patient group directions do not continue to meet the needs of some patients and there are others where independent prescribing would be the most appropriate option. As a recent scoping exercise and group has recommended that independent prescribing should be introduced for physiotherapists and podiatrists, it is likely that further developments will be forthcoming. However, the benefits of supplementary prescribing remain evident for this professional group and it is important that this continues to be recognised, even in the event of independent prescribing rights being granted. Case studies G, H and I provide practice examples of allied health professional supplementary prescribing.

Activity box 1.9

Consider the following examples of allied health professional practice. Decide if supplementary prescribing would be most appropriate:

Sammy is a hospital-based physiotherapist, specialising in musculoskeletal conditions.

Frances is a podiatrist, specialising in diabetic foot conditions, who regularly has to prescribe long-term antifungal preparations.

Frances is a radiographer who is lead for her hospital's lower gastrointestinal endoscopy unit. Patients often require 'one-off' prescribing of bowel preparations.

Optometrist prescribers

Optometrist prescribing programmes are validated by the General Optical Council (GOC) and are currently limited to three universities in the UK. Non-medical prescribing education for optometrists is somewhat different to the generic programmes offered to other professions, focusing very much on the speciality of optometry. All registered optometrists are able to administer and supply using specific exemptions but these are limited. Those optometrists wishing to administer, supply or prescribe beyond those exemptions must undertake specialist training that must be registered with the GOC (College of Optometrists 2009). In order to achieve this, legislative changes have now enabled optometrists to undertake three routes: additional supply, supplementary prescribing and/or independent prescribing. Additional supply has enabled appropriately qualified optometrists access to an extended list of exemptions. Supplementary and independent prescribing is undertaken using the same criteria identified for other non-medical prescribing professions. Case study J provides an example of optometrist prescribing in practice.

Patient group directions

It is important that clarification is provided in relation to the differences between prescribing and the use of PGDs. Prescribing is undertaken on an individual basis, taking into account the individual needs of a patient, based on a thorough and holistic assessment, resulting, where appropriate, in the generation of a prescription. The use of PGDs does not constitute prescribing, although it could be argued that the processes leading up to both the generation of a prescription and the use of a PGD are similar.

The preferred method by which patients receive medicines is to have them prescribed, on an individual basis, by a health professional who has been trained to do so (NPC 2004b). An alternative to this is the use of a PGD. It is not the intention of this discussion to provide a detailed account of the application of PGDs. Instead, the focus is on the differences between the two and the appropriateness of their use.

A PGD is defined as (NPC 2009, p. 11):

... a written instruction for the sale, supply and/or administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment.

The PGD therefore allows a healthcare professional to supply and/or administer a medicine directly to the patient. This can be done without the patient being required to see a prescriber, although a prescriber may have referred the patient in some instances. The health professional using a PGD is responsible for assessing the patient, just as a prescriber would in order to reach a decision about treatment. The difference in this assessment is that the health professional using a PGD undertakes the assessment against set criteria that determine if the PGD is appropriate (NPC 2004b). In the same situation, the prescriber's assessment would no doubt incorporate many of the criteria used for the PGD but would also incorporate information that is individual to the patient.

As the definition of a PGD states, the medicines are predetermined for an identified clinical situation. Prescribing, on the other hand, enables the health professional to take into account the individual needs of the patient, using these to decide on an appropriate treatment, which may or may not be the same as indicated in the PGD. The prescriber may also support this by tackling the long-term implications of the presenting clinical situation.

The necessity to determine whether the PGD, or prescribing, is most appropriate supports the reality that many services will function most effectively using a combination of both. Case study 9 provides an example of how the same clinical situation may be dealt with promptly and effectively by both methods, demonstrating a situation where prescribing would be preferable but where a PGD would enable a satisfactory outcome.

Although it is acknowledged that prescribing is the most appropriate option in most instances, it is also recognised that the use of PGDs, in a limited number of situations, can be advantageous for patient care, provided that it does not compromise patient safety (HRT 2006b). Immunisation is an example of such a situation. The criteria set across the PGD to determine if a vaccine is appropriate enables health professionals to administer vaccines safely and efficiently within busy clinics, without the necessity of every health professional being a prescriber.

Activity box 1.10

Access the following websites for in depth information on PGDs:

Full website (England): www.portal.nelm.nhs.uk/PGD/default.aspx
 NHS web website (Scotland): www.nes.scot.nhs.uk/pgds
 Health (Wales): www.wales.nhs.uk
 MHRA (All UK): www.mhra.gov.uk/index.htm

Product specific directions differ from PGDs in that they are specific to a named patient. It is important to briefly clarify the link between prescribing and patient-specific directions because many non-medical prescribers will use them within their prescribing role. A patient specific direction is defined by the Department of Health (2006b, p. 1) as:

... the traditional written instruction, from a doctor, dentist, nurse or pharmacist or independent prescriber, for medicines to be supplied or administered to a named patient...

As a non-medical prescriber, a nurse, midwife or pharmacist may direct a relevantly qualified person to administer or supply a medicine. This direction will be based on the independent prescriber's assessment and decision about diagnosis and treatment. An example of this in secondary care would include an instruction given on a patient's ward bag that:

Access to education programmes

Although many professionals reading this book will either be currently undertaking, or will have completed, a recognised programme of education in supplementary and/or independent prescribing, it is recognised that others will be using it to acquire information to help them to decide whether or not non-medical prescribing is appropriate for them. In many ways, the professional bodies governing the relevant professions have determined criteria that have simplified this decision. It is recommended that any professional considering undertaking an education programme in non-medical prescribing accesses the standards set by their own professional body, the links for which are:

- General Optometry Council: www.optical.org/en/our_work/Standards/index.cfm
- Health Professions Council: www.hpc-uk.org/assets/documents/10002367FINALcopyofSCPEJuly2008.pdf
- Nursing and Midwifery Council: www.nmc-uk.org/aDisplayDocument.aspx?documentID=1645
- Royal Pharmaceutical Society: www.rpsgb.org/pdfs/indprescoutcurric.pdf

However, a brief explanation of the criteria used in determining access to education programmes is provided below.

Criteria relevant to all

Health professionals must:

- be in a post in which prescribing will enhance their role and make better use of their skills
- be able to identify that the introduction of non-medical prescribing within their role will improve the quality of patient care
- be able to identify that the introduction of non-medical prescribing within their role will enable quicker and more efficient access to medicines for patients
- be able to prescribe within their practice area once the education programme is successfully completed
- have the ability to study at a minimum of degree level
- have the support of their employer
- have access to a budget from which the cost of their prescriptions will be met
- have access to continuing professional development
- be able to identify an appropriate doctor who has agreed to act as their designated medical practitioner (note that for nurses, midwives and health visitors undertaking the community practitioner prescribing V100/V150 programmes must **instead** be able to identify a practising prescriber who has agreed to act as their practice supporter; this may be another non-medical prescriber).

Nurse, midwife and health visitor-specific criteria

Nurses, midwives and health visitors must do the following.

Goal

To encourage a specialist community public health nurse or community specialist practitioner programme or already hold these qualifications.

Goal

To have practised for a minimum of 2 years in the area in which they intend to prescribe.

Goal

To have at least 3 years of post-registration clinical experience, with the last year being in the specialty/area in which they intend to prescribe.

Allied health professional specific criteria

Allied health professionals must:

• have at least 3 years relevant post-qualification clinical experience.

Pharmacist-specific criteria

Pharmacists must:

• have a minimum of 2 years appropriate patient orientated experience in addition to the pre-registration year after graduation

• be on the practising register.

Pharmacist specific criteria

Pharmacists must have been practising in the UK for 2 full years before they are eligible to start training for the therapeutic specialty qualifications.

Summary of the context of prescribing

When Reader has examined the context in which non-medical prescribing continues to develop in the UK, it is apparent that, although evolving, non-medical prescribing maintains its original vision of improving patient access to medicines through safe, effective and efficient prescribing. The achievement of this vision has relied on appropriate measures being made to the pressures placed on it. Figure 1.1 serves to highlight that the achievement of safe, effective and efficient prescribing results from a balance between these pressures and responses.

That pressures on prescribing are multiple. The identification of emerging safety issues, new public health targets and the resultant needs of the patient, professional

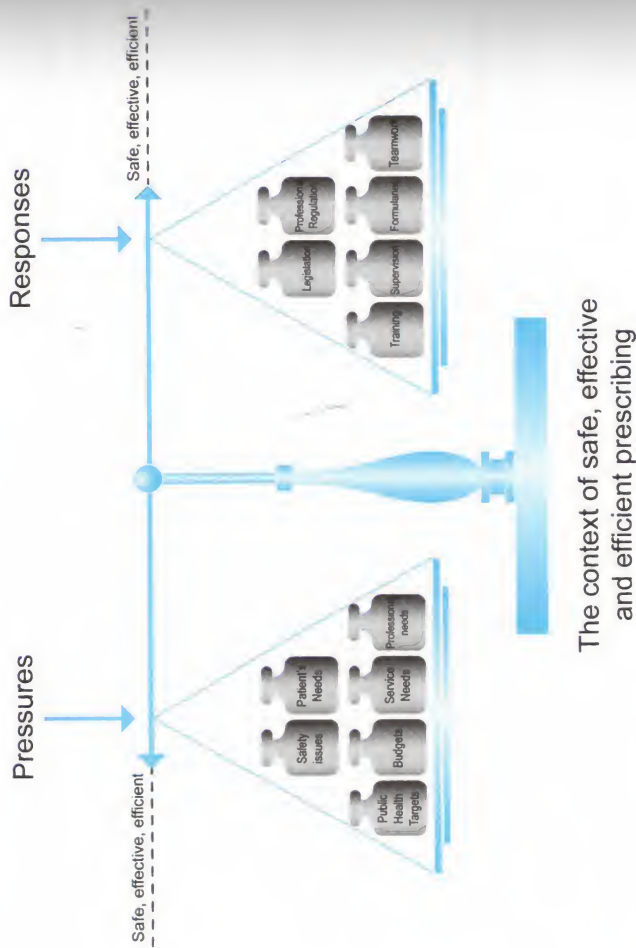


Figure 1.1 The balance between pressures and responses.

and service all require response within a limited budget. To ensure that prescribing is able to form an effective element of the health services' response to these pressures, a teamwork approach is important. CPD, which incorporates not only relevant education but also appropriate and effective supervision, is essential in order to promote evidence-based and cost-effective practice. As the context of prescribing continues to evolve, so must the support provided to prescribers by legislation and professional regulation.

Key themes: conclusions and considerations

Public health

Public health has been shown to be a responsibility of all health professionals. So that inequalities in health in the UK are addressed, public health targets must remain a consideration in all areas of practice. Non-medical prescribing provides an appropriate setting for considering public health issues

Consider how you, as an individual practitioner, can impact on public health targets. Evaluation of your own practice will highlight areas that can be developed to ensure that public health becomes an integral part of non-medical prescribing practice

Social and cultural issues

The current context of non-medical prescribing has evolved from a position where prescribing was seen as the domain of doctors. The process of change has involved social and cultural shifts on the part of both patients and health professionals. Much of this process has relied on effective communication and the development of a sound evidence base

Consider what measures you can take to further reduce the barriers to non-medical prescribing and to promote it as an effective tool in meeting the needs of the patient and the health service

Underlying principles

The prescribing principles have continued to support safe non-medical prescribing for over a decade

Consider each principle individually in order to evaluate how effectively you address them in practice. Dependent upon your experience as a prescriber, the consideration given to the individual principles on a daily basis is likely to differ. Reflecting on and revisiting the prescribing principles will aid both the novice and the experienced prescriber to ensure that their practice remains safe

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Chapter 2

Professional, Legal and Ethical Issues in Relation to Prescribing Practice

Ruth Broadhead

Learning objectives

After reading this chapter and completing the activities within it, the reader will be able to:

- 1 discuss the importance of maintaining professional responsibility and accountability in relation to prescribing practice
- 2 identify the sources and systems of UK law and its application in healthcare
- 3 critically analyse the relevance of moral and ethical theory in prescribing practice

A comprehensive understanding of professional, legal and ethical issues is a fundamental component of safe prescribing practice. This chapter therefore explores some of the complex issues that impact on safe, legal prescribing and identify judicious frameworks that guide and support practitioners in the complex principles of the prescribing process. In particular the chapter aims to identify what is and what is not legally permissible practice. The chapter is divided into three parts: Part 1: professional issues; Part 2: legal issues; and Part 3: ethical issues. However, the topics included in each of these sections have a significant degree of intercorrelation and issues should not be considered in isolation, but be examined concurrently, e.g. when studying aspects of consent or confidentiality, there are professional, legal and ethical issues to consider.

The law is ever changing and legislation is continuously open to shifting interpretation and amendment. Although the statutes, case law judgments and legal guidelines contained within this chapter are correct at the time of writing, a contemporary awareness of current for non-medical prescribers to keep abreast of changes. The legal rules of England and Wales are generally synonymous, yet Scotland and Northern Ireland have some discernible variants that are highlighted in this chapter where possible. It is, therefore, individual prescribers' responsibility to regularly update their knowledge of

the current legislation within their respective countries and to incorporate the appropriate legal guidelines into their own prescribing practice. The purpose of this chapter is, therefore, to heighten the awareness of the practitioner to the potential consequences resulting from failure to fully appreciate the significance of adhering to professional regulations, legislation and moral principles rather than transiterate legislation verbatim. A lack of appreciation by the prescriber of the concepts contained in this chapter can result in dire consequences for both the patient and the practitioner and, as such, the overall intention is to inform the non-medical prescriber sufficiently well to prescribe within professional, legal and ethical parameters.

In response to progressive developments in UK healthcare and with the consequential inception of non-medical prescribing, there have been significant requisite changes to the regulations and guidelines determined by the associated professional bodies. Legal frameworks relating to prescribing have been modified to take account of prescribers from disciplines other than medicine and dentistry and, as a result of these amendments, a more acute appreciation of professional accountability has evolved. Furthermore, the continuing expansion of non-medical prescribing has depended on changes being implemented with regard to education, professional regulations, and in the legal frameworks for the prescribing, supply and administration of medicines. Despite the successful augmentation of the non-medical prescribing initiative, prescribers still remain under scrutiny from associated professionals and the general public, not least because of the perceived inadequacy of prescribing training courses to address diagnostic skills (Avery and Pringle 2005, British Medical Association 2005), but also by the newfound litigious culture within the UK. However, educational programmes have responded to this criticism by incorporating into the curricula a major focus on clinical decision-making, professionalism, the legalities of prescribing and the ethical principles of patient-centred prescribing practice. It is now increasingly evident that the changing attitudes of service users and healthcare professionals are positive and remain key to securing the acceptance of this advanced role.

PART 1: PROFESSIONAL ISSUES

The regulatory framework for prescribing

As prescribers, just as we require a structured framework to guide the clinical prescribing process, we need a suitable directive to guarantee that we work to an approved standard in legal and professional terms. Table 2.1 illustrates the sources of professional regulations for practice, current legislation and guiding regulatory bodies that govern non-medical prescribing.

Medicines and prescribing

The Medicines Act 1968, Misuse of Drugs Act 1971 and Prescription Only Medicines (Human Use) Orders 1997 provide legislative guidance on the production, sale and use of medicines, including regulation on prescribing rights.

The Medicines Act 1968 governs the manufacture and supply of medicines and defines three categories of medicines:

Table 2.1 Legal and professional regulatory framework governing

Legislative	Professional	Regulatory
The Medicines Act 1968	Nursing and Midwifery Council (NMC): www.nmc-uk.org	Medicines and Healthcare products Regulatory Agency (MHRA): www.mhra.gov.uk
Misuse of Drugs Act 1971	General Pharmaceutical Council (GPhC): www.pharmacyregulation.org	Area drugs and therapeutics committees
Misuse of Drugs Regulations 2001	Health Professions Council (HPC): www.hpc-uk.org	
Prescription Only Medicines Orders (Human Use) 1997 and subsequent Statutory Instruments		

1. Prescription-only medicine (POM)

2. Pharmacy medicines (P)

3. General sales list medicine (GSL).

As the name suggests, POMs are only available with a prescription supplied by a medical authorised prescriber and are for the use of the patient named on the prescription only. Pharmacy medicines are available from a pharmacist, with over-the-counter sale without a prescription, and GSLs are available at other outlets such as supermarkets. However, supermarkets are legally bound to limit the number of certain drugs and may sell to single customers, e.g. analgesics. The Medicines and Healthcare products Regulatory Agency (MHRA 2010) identifies that:

Under medicines legislation, the general rule is that pharmacy (P) and prescription only medicines (POMs) may only be sold or supplied through registered pharmacies. They are subject to the additional requirement that they are sold or supplied in accordance with an appropriate practitioner's prescription. The law also restricts the administration of parenteral medicines which, if not self-administered, must be administered by a doctor or, in certain circumstances an independent nurse prescriber or a supplementary prescriber. Parenteral medicines can also be administered by anyone acting in accordance with the patient-specific directions of a doctor or, again in certain circumstances, an independent nurse prescriber or a supplementary prescriber.

Exemptions under the Medicines Act 1968 include a range of exemptions from these restrictions (MHRA 2010). These exemptions allow certain groups of health professionals, such as midwives or paramedics to sell, supply and administer particular medicines acting in patients. The MHRA state that:

These exemptions are distinct from prescribing which requires the involvement of a pharmacist in the sale or supply of the medicine. They also differ from the arrangements for Patient Group Directions (PGDs) as the latter must comply with specific legal criteria, be signed by a doctor or dentist and a pharmacist and authorised by an appropriate body.

Table 2.2 Misuse of Drugs Act 1971 Drug Classification

Class A	Heroin, cocaine, ecstasy, methamphetamine, LSD and psilocybin mushrooms
Class B	Cannabis, amphetamine, codeine and methylphenidate (Ritalin)
Class C	GHB, ketamine, diazepam, flunitrazepam, most other tranquilisers, benzodiazepines and anabolic steroids

The Misuse of Drugs Act 1971 is an Act of Parliament that governs the penalty for possession and supply of narcotics and psychotropic drugs. The Act clearly categorises three separate classes of drugs (Table 2.2).

The responsibility for listing, de-listing and grading of drugs is devolved to the current Home Secretary and penalties under the Misuse of Drugs Act 1971 vary for both the illegal and unlicensed possession of drugs and the possession of drugs with intent to supply. Prescribers are no less likely to be prosecuted under the Misuse of Drugs Act than other members of the healthcare professions or the general public, yet it is suggested that perhaps prescribers should be penalised more severely, due to the position of trust that they hold within society. Non-medical prescribers are responsible for upholding the credibility of their respective professions and are in a privileged position regarding the safe and legal management of medicines. Regulations for the storage, prescribing, supply and administration of drugs in the categories identified in Table 2.2 need to be stringent and those of us who are prescribers or administrators of these drugs should obtain a heightened awareness of the associated legislation and professional guidance. The prescribing of controlled drugs is discussed in more depth in Part 2 of this chapter.

Prescription Only Medicines Orders (Human Use) 1997 and subsequent Statutory Instruments/Amendments are successive modifications to the Medicines Act 1971 and detail contemporary changes to certain aspects of the legislation. Non-medical prescribers are required to keep abreast of these amendments to ensure that they are working in line with current guidelines. Changes can be located at the Office of Public Sector Information (see www.opsi.gov.uk) or from prescribers' respective professional bodies.

The MHRA is responsible for regulating medicines in the UK. This includes ensuring that medicines and medical devices are safe and for bringing prosecutions when medicines legislation has been broken. The MHRA is an executive agency in the Department of Health and its inception in 2003 was as a result of the amalgamation of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA). A fundamental aspect of the role of the MHRA is to oversee and promote the safe use of medicines and devices. They are also responsible for monitoring adverse drug reactions (ADRs) and taking appropriate action as necessary when they are identified. The Yellow Card scheme is a reporting system that was initiated in 1964 after the thalidomide catastrophe to facilitate a robust and timely information system to highlight potential and actual ADRs. It is a requirement of the scheme that ADRs be reported to the MHRA via the Yellow Card scheme by prescribers as soon as they are suspected. However, anyone can report suspected ADRs to the MHRA.

Drugs drugs and therapeutics committees are locally appointed groups responsible for developing and implementing national guidelines at a local level. Their terms of reference and locally devolved policies can be obtained from each of the committees in the 'practice' area of work.

Activity box 2.1

Find out where your local area drugs and therapeutics committee is located.

What are the members of this committee?

What policies have been developed by this group?

Professional codes

Non-medical prescribers are required to work within the boundaries of their own codes of conduct with the intention of providing high-quality standards of healthcare, adhering to the public and promoting professional credibility.

In gaining a prescribing qualification, practitioners should aim to be fully conversant with their codes of practice (Table 2.3), along with the associated legislation and applicable ethical principles. Nurses, midwives, pharmacists and those from allied health professions are duty bound to ensure that their professional development incorporates a robust appreciation of the parameters contained within their professional codes of practice because it is these codes that act as a principal set of rules and standards to guide their practice, including the prescribing process. It is perhaps significant to add that anecdotal evidence suggests that familiarisation with the content of codes of practice is poor or completely lacking in many potential prescribers, leaving them exposed to potentially intractable, but avoidable, problems. It could be argued that with the recent advent of an abundance of web-based information and the relevant documents being easily accessible for each profession, a lack of awareness would be an unsatisfactory state should prescribing practice be questioned. As the professional codes of practice for practitioners with a regulatory framework for prescribing, it is suggested that the acquisition of this additional skill should be founded on this inaugural knowledge.

Activity box 2.2

Obtain a copy of your own code of conduct. Look at the standards contained therein and:

Write down how you can ensure that you meet these standards as a qualified prescriber

Identify upon the benefits to your prescribing practice of reviewing the standards

Table 2.3 Non-medical prescribers' professional codes of practice

Nurses	<i>The Code: Standards of conduct, Performance and ethics for nurses and midwives (Nursing and Midwifery Council 2008a)</i>
Pharmacists	<i>Standards of Conduct, Ethics and Performance (General Pharmaceutical Council 2010)</i>
Allied health professionals	<i>Standards of Conduct, Performance and Ethics (Health Professions Council 2008)</i>

Accountability and responsibility

Accountability is synonymous with components of 'governance', in that organisations and individuals are held *accountable* for assuring quality standards are met in the care they deliver. The Nursing and Midwifery Council (NMC 2010a), the General Pharmaceutical Council (GPhC 2010) and the Health Professions Council (HPC 2008) all recognise clinical governance as 'a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care ...'. Therefore it is suggested that organisations place the accountability of prescribing practitioners high on the clinical governance agenda. The practical application of this is discussed further in Chapter 9.

Although it is clear that nurses, midwives, pharmacists and allied health professionals work with a fair degree of professional autonomy, it is evident that holding a prescribing qualification demands a higher measure of responsibility. The term 'accountability' is often misconstrued by healthcare professionals due to its ambiguity and multidirectional connotations, but is generally accepted as being a measure of *liability* for the practitioner's conduct. Savage and Moore (2004) identified that being 'accountable' describes certain relationships such as those with patients, those with organisations and those with oneself. Accountability can imply being responsible to someone or something and a resulting, definitive willingness to take the consequences of actions or inactions. Furthermore, as prescribing professionals, being held accountable can both motivate and explain our decision-making, but perhaps more so it allows us to accept or apportion blame for prescribing misdemeanours.

Professional indemnity

As a result of the demands brought about by the advanced role of prescribers, it could be said that there is an increased risk of claims being brought against us for mistakes in our clinical judgement, or indeed for clinical negligence allegations due to inadvertent acts and omissions in practice. Therefore, it is paramount that professional indemnity insurance be in place. Most nurses, pharmacists and allied health professionals such as podiatrists and optometrists obtain indemnity insurance through their recommended unions, most of which offer substantial cover for clinical negligence and legal representation. It is important to note that criminal acts, such as intentionally harming a patient or prescribing large doses of opiates for personal use, are not covered by professional

indemnity insurance. The Pharmacists' Defence Association (PDA), the Royal College of Podiatry (RCPh) and the British Chiropractic and Podiatry Association (BCPA), for example, offer their registered practitioners up to £5000 000 of cover for professional indemnity. The Medical Defence Union (MDU) now offers membership to healthcare professionals as other than doctors and dentists, including those undertaking cosmetic procedures such as injecting botulinum toxin. As prescribers, it is essential that, before undertaking an extended role, we ensure that adequate professional indemnity insurance has been secured.

Vicarious liability

The law makes a claim for damages, the employer is usually the defendant. As practitioners with new prescribing rights, our professional interest should be drawn to the condition that we hold under vicarious liability. Problems in practice may arise if a prescriber causes harm as a result of a prescriber's wrongful act that was not an activity authorised by the employer. It is suggested by British Employment Law (Emplaw) (2010) that there is no legal dilemma if the wrongful act done by an employee was in fact authorised by the employer. However, some contracts of employment and job descriptions are vague and it is not always obvious what exactly is authorised. In law, after a wrongful act, the dilemma would be whether or not an employer should be liable. (Emplaw 2010) further state that:

...in the late 1990's the basic test for deciding whether an employer should be held liable in such a case was to consider:

- whether the employee had used an unauthorised method to do a job he was authorised to do (in which case the employer would be vicariously liable) or
- whether he was simply doing something which was unauthorised (in which case the employer would not be vicariously liable).

In 2001 the House of Lords ruled in *Lister and ors v Hesley Hall Ltd* 2001

...important legal decisions should not turn on such semantics ...

As a result of the ruling in *Lister* it is now established that the correct test for whether vicarious liability is probable is to examine the connection between:

- 1 the nature of the employment and
- 2 the particular wrong and
- 3 if not another, looking at the matter in the round, it is just and reasonable to hold the employer vicariously liable.

In prescribing terms, therefore, we need to ensure that our prescribing practice is wholly authorised by our employers and stipulated as being a legitimate component of our job description. We should be aware that holding a prescribing qualification

does not automatically allow us to prescribe outside of the terms and conditions of our contracts and this should be discussed, agreed and signed up to. Gulliver (2006) suggests that some employment arrangements can be complex and that it would be sensible for non-medical prescribers to check that their contract of employment stipulates prescribing. Complexities in employment contracts may arise if a nurse, pharmacist or allied health professional is working for several GP practices, for example. The practitioner may not be working for any of them formally and may be employed by a primary care trust. It is therefore essential and sensible to ascertain in advance who will be responsible if a claim is made. Emplaw (2010) state that:

... more than one employer can share 'joint vicarious liability' in line with Court of Appeal decisions. None of this of course rules out the old traditional test as an aid to deciding whether the employer should be liable for unauthorised wrongful acts of his employees but does put it into a proper perspective.

In conclusion to this section, it is recommended that all non-medical prescribers take steps to:

- ensure that prescribing rights are explicitly detailed in contracts of employment and job descriptions
- confirm that vicarious liability is offered by your employer
- obtain adequate personal profession liability insurance.

Evidence-based practice

It is clearly stated in guidance from each of the non-medical prescribers' codes of conduct that prescribing practice must, wherever possible, be evidence based and in accordance with relevant national and local guidance. The RPSGB (2007) remind us that deviations from these policies must be justifiable and be in the best interest of the patient. This direction is also applicable to nurse and allied health professional prescribers.

As non-medical prescribers, it is good practice, and a professional expectation, to ensure that we are all adhering to the evidence bases, research and guidance available to us, but also maintaining our personal professional development (Department of Health (DH) 2009a). In a court of law, should we be called upon to defend our clinical decision-making, the procedure for ascertaining whether or not we acted appropriately would be judged and scrutinised in great detail, often with some vigour on behalf of the claimant. With all prescribing decisions it is undeniably imperative for us to contemplate our ability to endorse and validate our actions, should they ever be called into question. Gulliver (2006) suggests that with the added clinical responsibility of prescribing comes an inevitable increased risk of liability. One important issue that she highlights is the scope of prescribers' knowledge and the expectations of them if confronted by signs and symptoms that are obvious, but that do not fall within their area of expertise. All non-medical prescribers should bear in mind that, should the practitioner prescribe outside their field of competence, it is likely that a court of law will make instant and unsympathetic judgments against them. This is discussed in more depth in Part 2.

Fraud, criminal behaviour and whistleblowing

Prescribing rights, although well earned by the practitioner, could be seen as a professional privilege. With this licence comes an increase in the accessibility and availability of drugs which, to those with ulterior motives, could lead to fraudulent behaviour. The common inquiry (2010) produced six independent reports after the murderous acts of David Shephard, and two of these are relevant to us as non-medical prescribers. The Shipman Inquiry (Shipman Inquiry 2004a) was responsible for examining controlled drugs and how they are monitored in the community. The Chairman of the Report, Dame Janet Smith, made recommendations based on her findings including the implementation of systems for the management and regulation of controlled drugs and the conduct of those who operate these systems. The findings and recommendations contained within the Smith Report are very significant for prescribing practice, particularly for those working in pharmacies, palliative care, the community, intensive care units and accident and emergency departments, for example. The Fifth Report (Shipman Inquiry 2004b) focused on safeguarding patients and looked at the lessons learnt from Shipman in order to protect and regulate future practice. Again, the findings contained within it, although largely relevant to the regulation of doctors, are essential reading for all non-medical prescribers. The principles set out in the report guide practitioners on how to identify and raise concerns about serious professional misconduct, and the morality of ignoring such concerns, all of which should be considered by those who prescribe and manage drugs in the course of their work.

Whistleblowing in the NHS has long been a taboo subject and, historically, employees have been reluctant to expose substandard care or professional misconduct due to the risk of victimisation or retribution (DH 1999). More recently however, NHS Employers and as part of the Social Partnership Forum, have agreed to work alongside the main trade union, the Department of Health and the independent whistleblowing body, Public Concern at Work (PCAW), to produce new guidance for NHS staff. The new guidance, due for publication in June 2010, aims to investigate appropriate policy-making and the reluctance of staff to speak out against underperforming colleagues. Such reluctance from the Department of Health (2003a) that practitioners will be victimised, there still remains, however, a distinct element of unwillingness to partake in whistleblowing. This is perhaps increased by examples such as the case of nurse, Janet Hayward, who spoke out about neglect at the Royal Sussex Hospital and was subsequently removed from the NMC register for breaching patient confidentiality (Hayward 2009). As prescribers, it is recommended that we ensure our practice is always morally and wholly defensible. Furthermore, should we ever encounter bad practice, such as limited behaviour, we should be aware of the policies to guide us with whistleblowing in order to protect the interests of our patients and professional credibility.

Remote prescribing

'Remote remote prescribing' is twofold. First it refers to prescribing for patients who are personally remote' in the context of not being present with the prescriber in the same setting, such as being on the telephone. Second, the term can refer to areas of activity that are described as being 'geographically remote' such as islands in the

far north of the UK where healthcare services are poorly accessible and generally provided on the mainland.

The NMC (2008b) published a position statement in support of remote assessment and prescribing to improve access to medicines and enable choice in the delivery of healthcare. The General Medical Council (2008b) also acknowledged that 'from time to time it may be appropriate to use a telephone or other non-face-to-face medium to prescribe medicines and treatment for patients'. Although the latter guidance is aimed at doctors, the principles are analogous with those for other practitioners who prescribe via telephone, fax, email, video link or websites. It is highlighted that the prescriber must be satisfied that alternative means of prescribing for the patient in question are not available to them. It is a stipulation that appropriate dialogue is developed in order for the prescriber to establish a rapport with the patient to elicit a detailed history and gain informed consent. It is further suggested that, if all these conditions cannot be met, remote prescribing should not be undertaken. For some non-medical prescribers, this method of prescribing could become a significant means of providing a service to their patients. However, it may not be appropriate for other non-medical prescribers, particularly if the recommended criteria cannot be met. Kular (2010) highlighted that remote consultations are an important primary care tool, particularly for triage, acute conditions such as respiratory conditions and uncomplicated urinary tract infections, well controlled chronic conditions such as diabetes or asthma, follow-up after hospital admission, and providing results of diagnostic tests or health promotion.

Activity box 2.3

Within your practice area and considering available policy relating to remote prescribing:

- Identify when remote prescribing via telephone, text or internet may be appropriate
- Consider how you would ensure that you obtain sufficient information from the patient
- Identify how you would gain consent
- Critically evaluate if remote prescribing is equitable

The criteria contained within the NMC and General Medical Council (GMC) guidance relates to generic prescribing yet the MHRA (2008) has produced additional guidance on the supply and administration of Botox[®], Vistabel[®], Dysport[®] and other injectable medicines used in cosmetic procedures. They identify the term 'appropriate practitioner' for prescribers undertaking this role and these include a doctor, dentist and ('subject to certain limitations') a nurse or pharmacist independent or supplementary prescriber. There are explicit stipulations in the guidance regarding the supply and administration of these products, and it is recommended that the MHRA document

Hospital trusts and primary care trusts (PCTs) should produce their own transcribing protocol such as the example available from East Riding of Yorkshire Primary Care Trust (2007) and is a voluntary activity that can be undertaken only by certain practitioners as part of a holistic patient assessment. Practitioners authorised to transcribe should be competent to do so as assessed by the relevant trust and should have completed and signed a transcribing signature form that is thereafter held in their personnel records. Practitioners that are permitted to transcribe usually include registered community practitioner nurse prescribers, GPs and locality pharmacists, for example. All non-medical prescribers should be aware of their own transcribing protocol to ensure safe and legal practice. It is suggested that, if the requirements are not identical to those that have previously been prescribed, then staff must not transcribe. Furthermore, drugs that have been discontinued or are not clearly legible must not be transcribed. Staff are unable to transcribe the details of schedule 2 or 3 controlled drugs, e.g. opiates, amphetamines, barbiturates, and referral back to an independent prescriber must be made for complete re-writing. Local guidance for paediatric transcribing should be sought, but generally it is not recommended. Glare (2009) identified, in a study of medication errors in medical wards, that over half of the medication orders studied contained a prescribing or transcription error. Transcribing errors were classified as errors in the process of interpreting, verifying and transcribing medication orders; however, the incidence of preventable medication errors was low. In view of this, as prescribers we need to ensure that anyone who is transcribing our prescription orders are appropriately trained and competent to undertake the role safely. In legal terms, transcribing is not a means of prescribing itself, yet it could be perceived as being a component of the complete 'prescribing process' for some patients; e.g. a patient under the care of a non-medical prescribing specialist nurse in hospital could have a medication transcribed in the discharge process. Care should therefore be taken to ensure that transcribing staff understand the difference and practitioners undertaking this role should be accountable for their actions, as should those who delegate it.

Prescription form safety

The NHS Business Services Authority (2009) publishes guidance on the security of prescription forms. This section should be read in conjunction with the document *NHS Security Management Service Security of Prescription Forms Guidance* in order that the different types of prescribers familiarise themselves with the regulations appropriate to their place of work. In association with the above guidance, it is recommended that prescribers seek their own employers' protocols on the safety of prescriptions. It is evident that stolen prescriptions are most often used to obtain controlled drugs for recreational use or to sell for financial gain (NHS Business Authority 2009).

The security guidance available from the NHS Business Services Authority includes:

- Security features displayed on prescription forms including a 10-digit serial number, prescribers' personal details, anti-photocopying safeguards and UV-sensitive message
- Ordering, delivery, safe storage and stock control of forms
- Details of current forms for all types of prescriber
- Information on destroying obsolete forms

to reporting theft and fraudulent use of prescriptions

Prescribing procedure for theft of prescriptions including where to report, form to use and directions that may be given, e.g. to write in a specific colour (not always red) for a period of usually 2 months. The PCT/NHS trust local counter-fraud specialist should be informed and then inform local and surrounding pharmacies to alert them to the potential abuse of the stolen forms.

Prescription forms can be ordered and received only for use by nurses, pharmacists and other health professionals once the issuing trust receives notification of the appropriate consultation on the register of the prescribers' respective professional bodies. It is the responsibility of all non-medical prescribers to be fully conversant with the regulations and guidance available to them regarding the safety of prescriptions and to ensure that they use only the relevant prescription forms that have been issued to them.

PART 2: LEGAL ISSUES

THE UK legal system

The law affects virtually everything we do and almost all activities are legally regulated. The law sets standards of behaviour and can be defined as 'a rule or body of rules'. In society, rules can both guide and set standards for behaviour and can be classified as 'legal', 'social', 'ethical' or 'moral' rules. For example, a 'social rule' of the UK is that we drive on the left-hand side of the road or a 'moral rule' is that we do not ignore someone who may be asking for help. In prescribing practice, there are legal, social, moral and moral rules that we must abide by.

Activity box 2.4

As a prescriber, think of some examples of:

- legal rules
- social rules
- ethical rules
- moral rules

Do they have the same basic characteristics in that they are:

- general, i.e. they apply to everyone or a specific group
- prescriptive or prohibitive, i.e. they set standards of how things ought or ought not to be
- having clear standards of behaviour with which everyone must comply.

Some rules are ascribed the status of law. These rules must be definitive, consistent and understandable by everyone that they may affect. In other words rules as laws should not be vague or imprecise and they should be openly disseminated in advance, and, most importantly, they must be recognised and enforced by the courts. Therefore, law is a framework of regulations and rules that allow a society to self-govern, yet it is flexible, in that, should society's demands and needs change, the law too will change in order to reflect the current norms and values of a society. As society (or indeed health-care) alters, laws will be reformed in keeping with those changes, e.g. the Mental Health Act 2007 has a new definition of mental disorder and is a re-formation of the Mental Health Act 1983.

In the UK, laws can be the following:

- Formally enacted laws or statutes and are the main source of law
- Customary law or common law (derived from cases, i.e. 'case law'). Case law used to be the most important source of law and dates from the thirteenth century. It originates from local custom and is also known as 'judge-made' law. Case law has significantly contributed to the development of healthcare law and it develops through a system known as 'precedent' in which the courts examine and interpret similar cases and circumstances resulting in a judgment.

English law derives from three main sources:

- 1 Legislation (AOP)
- 2 Common law (Case law)
- 3 European law.

Legislation is drafted by Parliament and becomes law following royal assent. Statutes are otherwise known as Acts of Parliament or Primary Legislation and refer to specific areas, detailing the law AND the penalties for breaking such laws, e.g. the Medicines Act 1968. Amendments to Acts of Parliament are otherwise known as 'secondary', 'subordinate' or 'delegated' legislation and these can be:

- Statutory instruments
- Scottish statutory instruments
- Welsh Statutory instruments
- Statutory rules of Northern Ireland
- Church instruments
- Byelaws.

Secondary legislation is delegated to a person or body under authority contained in primary legislation, typically being conferred on ministers, the Crown or public bodies (e.g. Statutory Instrument 1992 No. 604. The Medicines Act (Amendment) Regulations 1992). Further reading on the UK legal system is recommended from the UK Statute Law Database (2010) at www.statutelaw.gov.uk.

The courts are the focal point of the UK legal system and can be classified in a number of ways:

- House of Lords
- Court of Appeal
- High Court
- Crown Court
- Magistrates' and County Courts
- Coroners' Court
- European Court of Justice
- Court of Human Rights.

The law in the UK is classified into the following types.

Private law

- Deals with the legal relationship between private individuals and organisations
- Includes regulating the provision of healthcare and provides a system of compensation for victims of malpractice.

Public law

- Comprises criminal law and the constitutional and administrative rules
- It governs how public bodies operate, e.g. NHS, local authorities, police force, the courts, civil service
- Protects the civil liberties and rights of citizens.

Further classification is as follows.

Civil law

- Comprises a very large area
- Includes every division of private law
- Includes all of public law except criminal law
- Actions in civil law are based on the principle that a remedy (usually monetary) be recovered from another party.

Criminal law

- Includes any behaviour (act or omission) that the state considers harmful or disruptive
- Offenders are punished (if caught)
- Some overlap between civil and criminal law may occur, e.g. a non-medical prescriber who treats a patient without consent is committing a *civil wrong* and a *criminal act*. If harm ensues, the practitioner can be both sued under civil law and face criminal charges.

Breaking a law will mean that we are legally blameworthy and deserve appropriate punishment. However, although we can all philosophise about laws, such as those

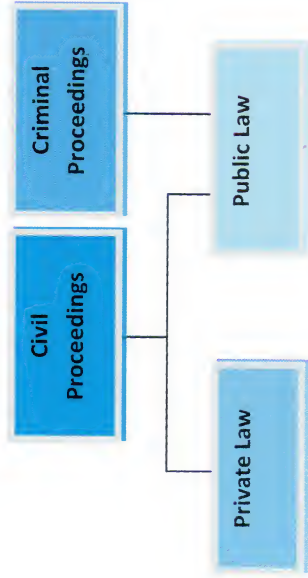


Figure 2.1 Civil law and criminal law proceedings.

around emotive subjects such as drug misuse or euthanasia, we must abide by the law in question, unless we are willing to be punished. As prescribers, for example, the 'law of the land' is that we do not prescribe class A drugs for ourselves to misuse, nor do we prescribe for patients in order to assist their suicide. However, for a crime to be committed, there needs to be two elements:

- 1 *Actus reus* (or the guilty act of prescribing inappropriately for self or others)
- 2 *Mens rea* (or a guilty mind or intention to self-harm or kill others).

Figure 2.1 demonstrates the classification of law in diagrammatic form to facilitate further understanding. In short, we have two possible directions for proceedings to be brought, i.e. under civil law or criminal law. Within civil law sits all of private law and all of public law except criminal law. Therefore civil proceedings can be brought under both public law and private law, whereas criminal proceedings will be brought under public law only. It is important for prescribers to have an introductory knowledge of the legal system in order that they develop an informative comprehension of how the law may affect them and their practices.

Further reading is recommended and information regarding the UK judicial system can be found on the UK Government website at www.direct.gov.uk.

Activity box 2.5

Consider your prescribing practice and reflect upon the relevance of law. To support critical reflection, it will be useful to consider the following questions:

- Do you have sufficient knowledge of how the law works?
- Do you feel protected by the law (why/why not)?
- In what instance may a criminal prosecution or civil suit be undertaken?

Negligence and duty of care

Tort law is a component of civil law and includes different types of action such as trespass, defamation, breach of statutory duty, nuisance and negligence. Therefore, clinical negligence is dealt with under the 'law of tort'. The Department of Health (2003b) identify tort as:

- ... an act or omission that causes harm to a person's property, reputation or interests ... and negligence is the specific tort involved in medical litigation.

In prescribing practice, should the practitioner cause harm as a result of his or her clinical decision-making and resultant prescribing, he or she could be held accountable under tort law. The law of negligence has been built up by the courts over years and derives from both *principles* and *precedents*. Judgments are based on specific legislation (statutes) and actual cases (common law). A petitioner who wishes to bring a claim in negligence has to meet the requirements set out by the House of Lords in a landmark case – that of *Donoghue v Stevenson* 1932, in which the 'duty of care' rule was applied. Herring (2008) identifies that most medical litigation is brought under the tort of negligence, but in order to proceed, three criteria need to be met:

- 1 The professional who is being sued owed the claimant a duty of care
- 2 The professional breached that duty of care
- 3 The breach of the duty of care caused the claimant loss.

Any professional owes a duty of care to his or her patient or client and non-medical prescribers are no exception to this. The duty of care by a healthcare professional to a patient is well established and Herring (2008, p. 94) further suggests that 'you owe a duty of care to anyone you may reasonably foreseeably injure'. As prescribers we need to take heed of this in every patient whom we treat and consider whether we could 'reasonably, foreseeably injure' them by our prescribing practice.

Once a duty of care is established, it is necessary to establish a breach of that duty. In law, negligence is ascertained on the balance of probabilities in that the practitioner acted as a 'reasonable person' would. The judgment in *Bolam v Friern Hospital Management Committee* 1957 stated:

- A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.

The *Bolam* test applies to all healthcare professionals and as a prescriber you would be judged against 'a responsible body' of non-medical prescribers undertaking the same role as yourself, should it be deemed that a breach of duty of care has occurred and a loss has resulted. In *Bolam*, the court said:

- Where the case involves some special skill or competence, then the test as to whether there has been negligence or not is ... the standard of the ordinary skilled man exercising and professing to have that special skill or knowledge.

In other words, prescribing is that 'special skill or knowledge' and you would be judged against your fellow prescribing peers. Therefore, negligence by a nurse, pharmacist or allied health professional (AHP) will be determined by the standard of the *ordinary* nurse, pharmacist or AHP. However, if the nurse, pharmacist or AHP professes to have specialist-prescribing skills, then the standard will be that of the *ordinary prescribing* nurse, pharmacist or AHP.

It is important to remember that a duty of care involves all aspects of practice including warning of those side effects, consequences and risks that the reasonably competent professional would have warned of as in *Chester v Afshar* 2005. As a prescriber, a fundamental responsibility of prescribing for others is to ensure that these risks are discussed with the patient or his or her advocate. Furthermore, it is clear that a 'reasonably competent' equivalent professional would not act unlawfully or outside their competence, and a prescriber who does act outside their field of competence is likely to be found guilty of negligence in a court of law should harm ensue.

Claims for clinical negligence are usually dealt with through a legal process resulting in compensation, known in legal terms as a 'remedy' and there have been recent reforms in respect of how such claims are dealt with in the NHS. Following recommendations from the Department of Health Chief Medical Officer's (CMO's) consultation document *Making Amendments* (DH 2003b) the NHS Redress Bill (DH 2005a) allowed the Secretary of State for Health to set up a redress scheme to 'apply to cases involving liabilities in tort' occurring from NHS hospital care (DH 2005b). These rules were appropriately placed in secondary legislation so that they could be easily amended in line with future changes within the realms of NHS service delivery, and it was anticipated that the subsequent NHS Redress Act 2006 would secure a fair and honourable system for compensatory resolution to hospital negligence claims. The NHS Redress Act 2006 received Royal Assent on 8 November 2006 and exists as:

An Act to make provision about arrangements for redress in relation to liability in tort in connection with services provided as part of the health service in England or Wales; and for connected purposes.

Although at face value, the Government's proposals for reform seemed commendable, if somewhat overdue, there has been some opposition to the philosophy of the Act in that some see it as a diluted 'quick fix' to addressing claims of negligence. Farrell and Devaney (2007), for example, insisted that a 'golden opportunity' had unfortunately been missed in providing a reasonable and equitable recompense for individuals who have 'suffered harm through medical treatment in the NHS'. However, on examination, it is argued that the Act offers a faster and more easily accessible scheme for numerous patients who are entitled to damages up to a certain value.

Under the NHS Redress Act, the NHS Redress Scheme must meet certain objectives. It should provide the following:

- an offer of compensation
- an explanation
- an apology
- a report detailing how similar cases may be avoided in the future.

So, it would appear that it is the Government's intention not only to provide compensation to the harmed individual(s), but also to take appropriate action to investigate how and why the particular harm ensued in order to improve NHS performance in ensuring the safety of patients. However, any settlement agreement provided under the scheme includes a waiver that prohibits the right of any claimant to bring civil proceedings 'in respect of the liability to which the settlement relates'. On balance, this appears to be a reasonable stipulation but does not take account of the possibility that a claimant may in fact become aware of related and contributory facts regarding their claim for damages after the settlement. Compensation could, in theory, be hastily accepted when in fact the resultant harm could have warranted further monetary remedy. It could be argued therefore that the Redress Scheme is, in effect, relying in part on the vulnerability of patients.

As prescribing practitioners, an awareness of the NHS Redress Scheme allows us to advise our patients if necessary but also to raise our sense of responsibility and vigilance in practice.

Prescription writing

A prescription is a legal document under the Medicines Act 1968. The law dictates which healthcare professionals can and cannot prescribe medicines, yet it also allows local arrangements to be developed to administer medicines by other means, to certain types of patients, in certain circumstances, by using patient group directions (PGD), for example. The use of PGDs is, however, not the same as prescribing. Non-medical prescribers are permitted to prescribe within the parameters of the current guidelines for nurses, pharmacists and AHPs and, at the time of writing, specific prescribing entitlements are as detailed in this section. Prescribers are required to keep abreast of changes in these entitlements as an essential part of safe practice and effective professional development. The National Prescribing Centre regularly updates information for prescribers on their website and includes specific facts on prescribing entitlements. The section 'Prescribing controlled drugs', in Table 3.5, outlines professional annotations and prescribing rights for nurses, pharmacists and AHPs.

The *British National Formulary* (BNF) provides clear guidance on prescription writing and the standard produced by all non-medical prescribers should always reflect the example contained within the current version of the BNF. It is recommended that this part of the chapter should be read in conjunction with the following sections of the BNF:

- How to use the BNF
- Guidance on prescribing
- Prescription writing
- Emergency supply of medicines.

In law, the **only** healthcare practitioners legally permitted to write prescriptions are:

- Doctors
- Dentists

- Suitably qualified independent nurse and midwife prescribers (nurses and pharmacists)
- Supplementary prescribers (nurses, pharmacists and AHPs)
- Community practitioner prescribers (V100 and V150) – limited formulary.

Guidance on ‘unlicensed’, ‘off-label’, ‘off-licence’ medicines

Unlicensed medicines are medicinal products that are not licensed for any indication or age group. An unlicensed medicine is one that does not have a valid marketing authorisation (i.e. licence) in the UK (NMC 2010b). The NMC Circular 04/2010 (NMC 2010b) provides nurse and midwife prescribers with guidance on prescribing unlicensed medicines. It should be noted that the information in this circular replaces Practice Standard 17 (17.1) of the *Standards of Proficiency for Nurse and Midwife Prescribers* (NMC 2006). The circular advises that previous legislation has been amended to allow nurse and midwife independent prescribers to prescribe unlicensed medicines for those in their care on the same basis as doctors, dentists and supplementary prescribers. Furthermore the Pharmaceutical Services Negotiating Committee (PSNC 2010) advise that the Drug Tariff Part XVIIIB (ii) has been amended in line with the regulations to clarify that pharmacist independent prescribers may also now prescribe unlicensed medicines for their patients. They do, however, emphasise that optometrist prescribers continue not to be able to prescribe unlicensed medicines.

The NMC (2010b, p. 2) state that certain criteria should be considered before prescribing unlicensed medicines and it is proposed here that pharmacist independent prescribers should follow similar guidance. These guidelines are as follows:

- Practice Standard 17 (17.1) of the Standards of proficiency for nurse and midwife prescribers (NMC, 2006) should be replaced with the following information; You may prescribe an unlicensed medication as an independent nurse prescriber providing:
 - You are satisfied that an alternative, licensed medication would not meet the patient's or client's needs.
 - You are satisfied that there is a sufficient evidence base and/or experience to demonstrate the medication's safety and efficacy for that particular patient or client.
 - You are prepared to take responsibility for prescribing the unlicensed medicine and for overseeing the patient's or client's care, including monitoring and any follow-up treatment.
 - The patient or client agrees to the prescription in the knowledge that the medicine is unlicensed and understands the implications of this.
 - The medication chosen and the reason for choosing it are documented in patient's or client's notes.
 - You seek, as necessary, professional advice, e.g. from a pharmacist or other authoritative clinical guidance to support your prescribing practice and the specification for the unlicensed medicine.
 - You must report suspected adverse drug reactions arising from unlicensed medicines to the MHRA and Commission on Human Medicines via the Yellow Card scheme.

Borderline substances

Borderline substances are mainly foodstuffs, such as enteral feeds and foods that are specially formulated for people with medical conditions, but also include some toiletries, such as sun blocks for use by people with conditions such as photodermatosis (NHS Purchasing and Supply Agency (PASA) 2010). A list of ACBS (Advisory Committee on Borderline Substances)-approved products and the circumstances under which they can be prescribed can be found in the BNF. Although this is a non-mandatory list, independent prescribers should normally restrict their prescribing of borderline substances to items on the ACBS approved list.

Emergency supply requests

Community practitioner nurse prescribers, nurse and pharmacist independent prescribers, all supplementary prescribers, doctors and dentists can also request, in an emergency, the supply of a prescription-only medicine that is not a schedule 1, 2 or 3 controlled drug, if they would otherwise be entitled to prescribe that drug. The prescriber must give an undertaking to furnish a prescription within 72 hours (PSNC 2010). Prescribers should always keep abreast of changes in their entitlements and more information on the prescribing rights of different health professionals can be found in the PSNC online Drug Tariff Resource Centre (see www.psn.org.uk)

Writing the prescription

Writing a prescription is just one of the options that a non-medical prescriber can choose when considering ‘What strategy’ in the NPC (1999) prescribing pyramid. Figure 2.2 suggests where prescribing and prescription writing fit into the prescribing process and



Figure 2.2 Prescribing and the prescribing principles. (Adapted from the National Prescribing Centre 1999.)

it could be vehemently argued that the act of prescription writing should never be considered earlier than this point.

Non-medical prescribers should not undertake this role without supervision until fully conversant with the specific inclusions and definitive configuration of the prescription sheet. Anecdotal evidence suggests that it is habitually misconstrued by students how convoluted prescription writing actually is, and many perceive it as a minor part of the prescribing process. In actuality, students do not always perform this part of the process particularly well. Typical errors include misspelling of drug names, incorrect doses, unclear instructions, missing patient details and illegibility. It is therefore advised that non-medical prescribers perfect prescription writing before qualification and annotation on the register. Table 2.5 summarises the key requirements for safe and accurate prescription writing.

It is suggested by Weaver (2006) that Latin abbreviations should be avoided and, just as we should not abbreviate the names of drugs, nor should we abbreviate the specific instructions to both the pharmacist and the patient. Latin abbreviations as detailed in Table 2.6 cannot be translated completely accurately so good practice is to write the prescription in full, using English language. Weaver (2006) argues that 'the continued use of abbreviations often shortcuts medication safety' and advocates that the use of abbreviations in prescription writing be withdrawn. He suggested that organisations and disciplines that continue to use abbreviations in prescribing practice often do so because it is 'the way it has always been done'. Perhaps it could be suggested here that it is often difficult to change practice, particularly as the use of Latin can and is still deemed an almost elite, exclusive skill and language, used by health professionals, that is difficult to relinquish. Weaver (2006) further identifies rationale for avoiding Latin abbreviations and offers examples whereby misinterpretation can arise to the detriment of patient safety and prescriber credibility.

The following excerpt from Weaver's (2006) article demonstrates the dangers of using abbreviations:

A recommended total daily dose of 2400mg of ibuprofen should be prescribed as 600mg every 6 hours rather than 600mg q.i.d. (quarter in die) for several reasons. With the Latin directions, the patient could take all 4 doses before noon and still feel that he or she was in compliance with the q.i.d. directions. Also, if your handwriting is like that of most busy doctors, the pharmacist or nurse might misinterpret the q.i.d. for q.4 h. (quaque quarta hora). That would result in 6 doses of 600mg in a day and a total of 3600 mg/day of ibuprofen, which is well beyond the recommended adult daily dose of 2400mg. Thus, modern, safe prescribing practices discourage the use of Latin abbreviations such as b.i.d. (bis in die), t.i.d. (ter in die), h.s. (hora somni), p.c. (post cibum), and a.c. (ante cibum) and encourage the use of clear wording such as every 12 hours, every 8 hours, at bedtime, after eating, and before eating a meal, respectively'.

Although it is not illegal to use Latin abbreviations, it should be avoided on prescriptions, particularly if hand-written, unless the prescriber can guarantee that their instructions are clearly legible and that the pharmacist can accurately interpret those instructions. However, it is suggested here that, although the generic use of mutually recognised abbreviations in healthcare as such is an essential form of shorthand for

Table 2.5 Prescription writing guidelines

Only prescribe what you are qualified to within your own competencies
Some prescriptions may be computer generated
Write legibly and in indelible ink (black preferably)
State patient's full name, address, age, date of birth (years and months for under 12s is a legal requirement)
Clearly state the name (generic wherever possible) of the prescribed item, its formulation, strength, quantity, dosage and frequency
Do not use abbreviations (see below)
Use a line to distinguish between items
State clear directions
It is good practice to write 'No more items on this prescription' if there is unused space
Block out left-over space with a straight a line or Z
Legible signature (electronic signatures not permitted)
Date the prescription
Dose
For preparations to be taken 'as required', a minimum dose interval should be specified (e.g. 4 hourly)
For preparations to be taken 'as required', a maximum dose should be specified (e.g. No more than 8 tablets in any 24 hours)
Avoid unnecessary use of decimal points (e.g. 5.0 mg)
Frequency
For preparations to be taken at frequent intervals, a time period between doses should be specified (e.g. 1 capsule every 6 h)
May need to be agreed with the patient/parent/carer depending on normal routine
Quantity
Quantities of 1 gram or more should be written as 1g, 1.5g, 2g, etc.
Quantities of less than 1 gram should be written in milligrams (e.g. 500 mg and NOT 0.5 g)
Micrograms should be written in full and not abbreviated (e.g. 50 micrograms and NOT 50mcg)
Quantity should generally reflect pack sizes from the <i>British National Formulary/Nurses' Prescribing Formulary</i>
Further considerations
Indicate the number of days of treatment required in the box provided on NHS forms
This does not apply to items directed to be used as required – the quantity to be supplied needs to be stated
Although directions should preferably be in English without abbreviation , it is recognised that some Latin abbreviations are still used (see Table 2.6)

Adapted from guidance in the *British National Formulary* (BMA and RPSGB 2010).

practitioners, non-medical prescribers, particularly novice prescribers, should learn to write their scripts in full as a matter of course.

R The symbol Rx has long been used to represent 'prescription' and its origins are thought to lie in the Latin for 'recipe' or more literally 'to take'. Again, the use of this

Table 2.6 Latin abbreviations in prescribing

a.c.	ante cibum (before food)
b.d.	bis die (twice daily)
o.d.	omni die (every day)
o.m.	omni mane (every morning)
o.n.	omni nocte (every night)
p.c.	post cibum (after food)
p.r.n.	pro re nata (when required)
q.d.s.	quater die sumendum (to be taken four times daily)
q.q.h.	quarta quaque hora (every four hours)
t.d.s.	ter die sumendum (to be taken three times daily)
t.i.d.	ter in die (three times daily)
stat	immediately

symbol is widely used, yet its meaning and that of other abbreviations is open to misinterpretation by the user and the reader. It is suggested that, due to the risk of ambiguity and perhaps detrimental mistakes, non-medical prescribers limit or decline their use.



Activity box 2.6

Using the appropriate template for your professional group (Appendix 1) practice writing safe, accurate and legible prescriptions for the patients below:

- 1 Write a prescription for Sam, a 45-year-old man who has been smoking 20 cigarettes a day for 30 years and wishes to give up. He has heard about nicotine patches. He is generally well and takes no other medication.
- 2 You see Ethel, aged 76, in A&E after a fall. She sustained a Colles' fracture and has a plaster of Paris *in situ*. Write a prescription for some analgesia to take home. She has type 2 diabetes and takes metformin 500mg three times daily.
- 3 Sharon, aged 31, presents at the pharmacy with constipation. She is 26 weeks' pregnant and has not had her bowels opened for 5 days. She is extremely uncomfortable. What would you advise? If prescribing, write a prescription.
- 4 Jack is 18 and is an intravenous drug user. He presents with cellulitis of his left forearm. Apart from intravenous heroin, he takes no other medication. Write a prescription for appropriate treatment of his cellulitis.
- 5 Mary has recurrent vaginal discharge. It is itchy and has previously been diagnosed as 'thrush'. She has used the cream she was given 6 months ago with no effect. Write a prescription for this woman.

Prescribing controlled drugs

As with the previous section, this element of the chapter should be read in conjunction with the following part of the current BNF:

- Controlled drugs and drug dependence
- Emergency supply of medicines.

The Misuse of Drugs Act 1971 prohibits certain activities in relation to 'controlled drugs', in particular their manufacture, supply and possession. The penalties applicable to offences involving the different drugs are graded broadly according to the 'harmfulness' attributable to a drug when it is misused' and for this purpose the drugs are defined in the three classes identified in Table 2.2. Furthermore, there are limitations on the prescribing of controlled drugs, with some non-medical prescribers only being permitted to prescribe controlled drugs under certain circumstances and others being currently prohibited from prescribing any controlled drugs. This is detailed in Table 2.7.

The Misuse of Drugs Regulations 2001 define the classes of person who are authorised to supply and possess controlled drugs while acting in their professional capacities, and lay down the conditions under which these activities may be carried out. In these regulations, drugs are divided into five *schedules* each specifying the requirements governing such activities as import, export, production, supply, possession, prescribing and record keeping that apply to them. Occasionally, it may be necessary for a prescriber to request an emergency supply of medicines for their patient. However, the Prescription Only Medicines (Human Use) Order 1997 does not extend to controlled drugs, except for phenobarbital sodium for the treatment of epilepsy.

As the legalities, regulations and nuances of controlled drug prescribing is ever changing, it is suggested that the reader keeps abreast of the amendments by always using the most appropriate guidance for the field of healthcare within which they are employed. Further information can be obtained from the current version of the BNF and accessing contemporary information via professional bodies: the National Prescribing Centre (NPC) publication *A Guide to Good Practice in the Management of Controlled Drugs in Primary Care* (NPC 2009) and the Department of Health's (2007) document *Safer Management of Controlled Drugs*. For those prescribers working within or in partnership with care homes, the Care Quality Commission (2010) produce guidance in their document *Management of Controlled Drugs in Care Homes* that can be accessed via their website (www.cqc.org.uk).

The chapter continues with an examination of some of the legal issues of prescribing that could also be regarded as ethical considerations. Therefore, the reader is guided towards studying the next section from both a legal and an ethical perspective.

Legal aspects of autonomy and gaining consent

Purposeful evaluation of patients' autonomy and their ability to consent or refuse treatment is one of the main principles of prescribing. Anecdotally, prescribers can recoil from this important aspect of prescribing practice, perhaps in part due to a lack of awareness of the concepts or the lack of ability to assess the patient in the absence of transparent guidelines. Many practitioners wrongly assume that the assessment of a patient's mental capacity concerns only those patients with mental illness or learning disabilities. In reality, capacity to consent concerns all of us, and we, as prescribers, should be competent and confident to assess all of our patients' ability to consent at

Table 2.7 Prescribing rights and controlled drugs

V100 nurse Community practitioner prescriber <i>with</i> specialist qualification	Formulary and entitlements <i>Nurse Prescribers' Formulary for Community Practitioners</i> <ul style="list-style-type: none">• Cannot prescribe controlled drugs
V150 nurse Community practitioner prescriber <i>without</i> specialist qualification	Formulary and entitlements <i>Nurse Prescribers' Formulary for Community Practitioners</i> <ul style="list-style-type: none">• Cannot prescribe controlled drugs
V300 nurse Independent and supplementary prescriber	Formulary and entitlements <i>British National Formulary</i> <ul style="list-style-type: none">• Nurse independent prescribers are restricted by current legislation to independently prescribe only certain controlled drugs solely for specified medical conditions according to BNF nurse prescribers' formulary – nurse independent prescribing• Nurse supplementary prescribers can prescribe any schedule 2–5 controlled drugs for any condition within their competence, as part of a patient specific, written clinical management plan (CMP) agreed with a doctor
Pharmacist Independent and/or supplementary prescriber	Formulary and entitlements <i>British National Formulary</i> <ul style="list-style-type: none">• Pharmacist independent prescribers are not yet able to independently prescribe any controlled drugs• Pharmacist supplementary prescribers can prescribe any schedule 2–5 controlled drugs for any condition within their competence, as part of a patient specific, written CMP agreed with a doctor
Optometrist Independent and/or supplementary prescriber	Formulary and entitlements <i>British National Formulary</i> <ul style="list-style-type: none">• Optometrist independent prescribers are able to prescribe any licensed medicine for ocular conditions affecting the eye, and the tissue surrounding the eye, within their recognised area of expertise and competence, except for controlled drugs or medicines for parenteral administration• Optometrist independent prescribers cannot prescribe controlled drugs• Optometrist supplementary prescribers can prescribe any schedule 2–5 controlled drugs for any condition within their competence, as part of a patient specific, written CMP agreed with a doctor
Chiropodist/Podiatrist Supplementary prescriber	

Formulary and entitlements

British National Formulary

- **Chiropodist/podiatrist supplementary prescribers** can prescribe any schedule 2–5 controlled drugs for any condition within their competence, as part of a patient specific, written CMP agreed with a doctor
- **Note:** registered chiropodists with the appropriate annotation to sell, supply and administer medicines may obtain packs of certain wholesale medicines from a registered pharmacy for the chiropodist to sell or supply to their patients. This is different to prescribing (RPSGB 2009)

Physiotherapist/Radiologist

Supplementary prescriber

Formulary and entitlements

British National Formulary

- **Physiotherapist supplementary prescribers** can prescribe any schedule 2–5 controlled drugs for any condition within their competence, as part of a patient specific, written clinical management plan (CMP) agreed with a doctor

Adapted from information from the National Prescribing Centre (2010).

any given time. In view of the complexities of autonomy and consent, a large part of this section is dedicated to this issue.

The NPC's prescribing pyramid (NPC 1999) directs the prescriber to 'consider the patient' in step 1. A component part of 'considering the patient' involves the prescriber respecting the person's autonomy or acting as his or her advocate and assessing willingness and ability to consent. Educational programmes for non-medical prescribers promote the use of the NPC model in order to structure the prescribing process, yet it would seem that although the NPC makes reference to considering the patient 'holistically', the assessment of mental capacity, autonomy or gaining consent appears implicit and therefore could potentially be overlooked or trivialised. It is the prescriber's responsibility to ensure that these principal facets of the consultation are always allowed sufficient consideration.

Paternalism

Traditionally healthcare practice has been dominated by a paternalistic approach to decision-making. Practitioners using a paternalistic approach make decisions on behalf of the patient with little or no consultation or agreement (Maude P, Hawley G 2007, cited in Hawley 2007). In recent years, it is noted that doctors, nurses and other practitioners deemed this approach an appropriate and acceptable means of delivering healthcare. Today, however, with the advent of patient involvement, choice and a greater emphasis on patients' right to autonomy, a paternalistic approach is not as fervently conventional. Jefford and Tattersall (2002) identify that the literature generally suggests that most patients want as much information as possible and will seek it out from various sources, yet, further to this, Jefford et al (2005) argue that, in some

circumstances, clinicians may have to adopt a paternalistic approach to information giving when the information that they give may cause detrimental effects to their patient's wellbeing. The example that Jefford et al (2005) use is the withholding of information about unavailable, expensive cancer treatments that the patient could never afford to purchase. As suggested, much of the current literature concerning paternalistic approaches to healthcare does in fact support autonomy rather than paternalism, yet others believe that a paternalistic approach may be welcomed by some patients when developing their treatment plan. Often the patient will respect the practitioner's knowledge and skill in diagnosing their illness and willingly accept their judgement in deciding how to treat the presenting complaint. It could be argued that this approach is not paternalistic, but, in actual fact, an illustration of the trust within the prescriber-patient relationship. In support of this assumption, Edwards and Elwyn (2009) remind us that 'paternalism' is not intended to be 'objectionable per se', but rather that it is motivated by our desire to act with the patients' best interests at heart and is more about the adoption of parental, protective attitudes towards our patients. As prescribers, therefore, we need to acquire the ability to identify when a paternalistic approach to our patients is either inappropriate or justified.

Defining autonomy

Autonomy is a term that is associated with ideas such as self-determination, self-government and choosing one's own moral position (Beauchamp TL 1997, cited in Hendrick 2000) and can be defined as the person having the capacity to think, decide and act independently, without hindrance (Gillon 1985). Respect for autonomy is considered to be one of the most fundamental of moral principles (Hendrick 2000) yet, in relation to prescribing practice, it can be fraught with difficulty. One such problem is that patients are unique, populations are diverse and autonomy is variable, yet there is a significant group of people in whom autonomy is absent, compromised or undeveloped, which immediately presents us with a challenge. From a prescribing perspective, when assessing our patients and gathering information, it can often be assumed by practitioners that autonomy is present, yet it can equally be assumed to be absent in particular individuals such as those with mental illness, elderly people and children. It is suggested here that insufficient attention is paid to patient autonomy in some cases, perhaps because the consultation appears uneventful and straightforward. The utilisation of an appropriate consultation model may go part way to ensuring that autonomy is always assessed.

Dworkin (1989) characterised autonomy as 'the capacity of a person to critically reflect upon, and then attempt to accept or change, his or her preferences, desires, values and ideals'. Although this is a somewhat idealistic view of autonomy, our aim as prescribers should be to capture the essence of Dworkin's (1989) ideal as far as is attainable with our patients, while also recognising that autonomy is unrealistic and unachievable for some individuals such as those with dementing illness, people who are unconscious, mentally impaired individuals or neonates. As prescribers we need to aim to sufficiently respect and protect the autonomy of individuals in prescribing decisions or indeed act with the patient's best interests at heart if self-determination is absent.

The Kantian view of autonomy is that all people have unconditional worth (Beauchamp and Childress 2001) and that each person has the capacity to determine his or her own moral destiny. Immanuel Kant (1724-1804) expressed that an individual's autonomy is violated when he or she is merely treated as a means to achieving another's goals, with no consideration for his or her own personal goals. An example of this theory in today's terms and in prescribing practice is in a situation whereby a carer's goal may be to request that the practitioner prescribes sedating medication to a relative in order to ease the burden of care. Furthermore, patients may be prescribed particular medication in order to satisfy a prescriber's ulterior motives, as in the case of Harold Shipman. It is paramount that prescribers and prescribing practice be monitored appropriately to avoid prescribing that ignores the rights of the patient.

However, putting aside the potential abuse of prescribing rights, it could be suggested that, although Kant's concept of non-violation of a person's right to choose is honourable, it has to be established whether this can always be achieved in prescribing practice. It would be fair to argue that, despite acknowledging the patients' absolute right to autonomy, in healthcare it is possible only to maintain a patient's right to choose up to a certain point. Fallowfield et al (1994) reasoned that, in many circumstances, clinicians are best placed to make the overall decision in a treatment context and the skills and knowledge of non-medical prescribers could be seen as the rationale to underpin this school of thought. Furthermore, Tingle and Cribb (2002) recognised that patients often expect the healthcare professional to make decisions for them, including whether they need to have certain clinical interventions or take prescribed medication. In other words, some patients are quite content to relinquish their autonomy, in favour of the clinician's professional judgement. As prescribers, it could be suggested that this is evident in many, if not most, of our prescribing consultations.

Kottow (2003) recognises that autonomy has previously been 'hailed as the foremost principle in bioethics', but historically patient care has been subject to medical paternalism because the doctor was considered to be better qualified to make medical decisions than the patient, who can, according to Kottow, be 'distracted by illness'. Kottow further argues that the assumption that the sick person is not fully autonomous could be viewed as biased and unsubstantiated. Moreover, he states that, although it is undisputed that healthcare professionals may possess a sound clinical knowledge base, they habitually lack the ethical understanding and qualifications to allow them the prerogative to make decisions for others. It would then be fair to suggest that, in order to function effectively in the role of a non-medical prescriber, it is essential to become fully conversant with the principles of law and ethics.

A further premise is that it is well documented that respect for autonomy cannot always be observed in certain individuals. Our obligations as healthcare professionals to respect autonomy cannot possibly extend to those individuals who are considered non-autonomous, e.g. incapacitated, immature or severely mentally ill individuals. It is the responsibility of the prescriber to identify this inability in their patients and act in the person's 'best interests'. Interestingly, Beauchamp and Childress (2001) list 'drug-dependent persons' as being non-autonomous. This viewpoint is ambiguous and controversial, in that it would be fairer to say that a person 'under the influence of certain drugs' is temporarily non-autonomous. To clarify this argument, a 'drug-dependent' person could be anyone from an individual with one or more chronic diseases who is

reliant on certain drugs for continued survival or control of symptoms, to a heroin addict who, although dependent on it, has long periods of lucidity and, hence, the mental capacity to make decisions for himself. Significantly, Gillon (1985) stated that when assessing whether a patient is 'sufficiently autonomous' we should judge the capacity of the *individual* rather than label certain groups as capable of making decisions for themselves. This allows for those less clear-cut cases where an individual's autonomy may be compromised or underdeveloped, such as in unconscious individuals or children. Assessing the person as an individual affords us the authorisation to assess whether the patient is 'sufficiently autonomous' in a certain situation. We need to be aware, as prescribers, that in these situations the capacity to consent is not always static because an individual's autonomy and resulting capacity to consent can fluctuate.

The importance of consent

The following section should be read together with the Department of Health's document *Reference Guide to Consent for Examination or Treatment* (DH 2009b).

Obtaining consent for clinical interventions is a fundamental consideration in healthcare and particularly pertinent to the role of prescribers. Not only does the prescriber have to take a complete and thorough history, but examination of the patient and clinical investigations are often also required to confirm a diagnosis and agree a management plan. In order to perform all aspects of this process, suitable consent must be obtained. It is suggested that patient consent is valid only where the individual is competent to give it, has been properly informed and has agreed without coercion (GMC 2002). It should be made evident for all non-medical prescribers and students that gaining consent is a substantial component of prescribing practice which cannot and should not be superficially considered. To aid our practice, published guidelines in respect of consent are in abundance from each of the respective professional bodies and from the Department of Health, and it is the assimilation of these guidelines that is vital for legal, safe and ethically sensitive prescribing practice.

Dimond (2009, p. 19) identified different forms of consent and states that:

Consent is the agreement by a mentally competent person, voluntarily and without deceit or fraud, to an action which without that consent would be a trespass to the person ...

It is interesting to note that Dimond's definition of consent identifies a number of issues that need to be considered by the prescriber in the first instance: first, there needs to be 'agreement'; second, the patient must be deemed 'mentally competent'; third, agreement needs to be given 'voluntarily'; and fourth the prescriber has to act in a way that does not conceal any 'deceit or fraud'. Should any of these components be missing, the prescriber could be liable to answer to an accusation of 'trespass to the person'. When examined in more depth, the prescriber may feel apprehensive that each of these areas of consent alone is complex and laden with ambiguity, imprecision and possible misinterpretation.

Activity box 2.7

In your own area of practice, and using a model of reflection, write down an example of when you have obtained consent from a patient. Consider the following:

- 1 Was there satisfactory agreement?
- 2 Was the person mentally competent?
- 3 Was consent given voluntarily?
- 4 Was there any deceit or fraud?
- 5 In prescribing practice, could your method of gaining consent be deemed robust?

Consent in adults with capacity

There are various terms and distinct categories of consent and, in understanding the differences, the prescriber will feel more confident to assess the ability of patients to consent or refuse treatment. In prescribing it is good practice to document, however labourious, the nature of consent gained (Gulliver 2006).

Implied consent

This is otherwise referred to as 'non-verbal consent' and it is characterised by the patient displaying behaviours of acquiescence to a procedure such as having a blood test or their blood pressure taken by offering their arm. The GMC (2008a) warn, however, that 'you should be careful about relying on a patient's apparent compliance with a procedure as a form of consent. For example, the fact that a patient lies down on an examination couch does not in itself indicate that the patient has understood what you propose to do and why'. The RPSGB (2007c) state that in implied consent 'the patient indicates their consent without writing or speaking, for example, a patient who brings their prescriptions to you for dispensing'. In prescribing practice, it is suggested here that the use of implied consent is limited and unsafe with regards to the actual prescribing of treatments, because, in an ideal situation, a verbal exchange and discussion of those treatments will take place. However, implied consent may be evidently used in the clinical examination of patients, yet the practitioner should always be certain that consent is, in actual fact, *bona fide*.

Verbal consent

This is the type of consent that is used most readily by healthcare professionals in the course of their work. Nurses, pharmacists and AHPs rely on patients to verbalise their consent in response to the questions that they may ask of them. A resounding 'yes' or 'no' from the patient would quite easily confirm or refute agreement to a plan of treatment and it is this form of consent that would be sought in many prescribing situations. However, as Dimond (2009) highlights, should any discrepancy arise as to whether or not valid consent was gained, in the absence of witnesses, it would be the word of the

prescriber against that of the patient. Therefore, in prescribing practice, perhaps we need to consider more robust methods of safeguarding both our patients and ourselves.

Written consent

This is that in which, as the name implies, an agreement is given in writing and this is considered to be the most transparent form of gaining consent. Dimond (2009) suggests that written consent can be viewed as good evidence that the person agreed to the treatment by providing a signature. The GMC (2008b) suggest that 'in cases that involve higher risk, it is important that you get the patient's written consent. This is so that everyone involved understands what was explained and agreed. By law you must get written consent for certain treatments, such as fertility treatment and organ donation and you must follow the laws and codes of practice that govern these situations'.

Written consent forms should include details of the treatment or procedure and it is against this information that the patient agrees or disagrees to it. In supplementary prescribing, the clinical management plan can be viewed as detailing sufficient information for the patient to sign up to it. As part of the tripartite agreement among the independent prescriber, supplementary prescriber and patient, signatures are required to legitimise and seal the plan as a mutually consensual care pathway. However, although written consent is the ideal in supplementary prescribing, and easily orchestrated, it would be unfeasible to obtain written consent in all independent prescribing consultations, mainly due to time constraints. In written consent, in addition to gaining a signature, the patient should be provided with details of any significant risks from the treatment or procedure in order that they can make an informed decision. The BMA (2009), in their guidance, confirm that there is no legal requirement to obtain written consent, but it may be advisable in some cases. As a non-medical prescriber, it is an independent professional judgement that needs to be made depending on the circumstances of the consultation. It is important to remember that the consent form documents only that some discussion about the treatment has taken place and it is advised by the BMA that the nature of any discussion is recorded in the patient's records.

Informed consent

This is a term that is used widely in healthcare law and ethics. Informed consent is defined by the Royal College of Nursing (RNC 2005, p. 5) as 'an ongoing agreement by a person to receive treatment, undergo procedures or participate in research, after risks, benefits and alternatives have been adequately explained to them'. It is, however, a complex principle that many healthcare professionals fail to comprehend in any great depth. Anecdotal evidence suggests that the term 'informed consent' is generally used superficially, even nonchalantly, with very little evidence of an appreciation of its precise meaning among healthcare professionals. It appears that in practice there are varying degrees of detail given to patients before clinical procedures and treatments, and it could be argued that there are a variety of reasons why this is so. As a consequence, it is suggested here that consent is often obtained inadvertently from patients, without the benefit of true understanding of the treatment, procedure or examination. Moreover it is further suggested that, without any prior consideration of the implications for either the healthcare professional or the patient, prescribing would be unsafe. This is com-

pletely unsatisfactory, but common practice. Therefore, informed consent is explored in greater depth here to secure sound understanding.

Although much has been written on informed consent and its importance in protecting patient autonomy, a great deal of the literature is unconvincing and supported by poor arguments, yet it remains an essential facet of prescribing practice. O'Neill (2003) acknowledges that there are significant limitations as well as strengths in the procedures that we undertake in order to obtain informed consent, and suggests that all healthcare practitioners should seriously recognise these in order to support their clinical practice and professional accountability. Patients should be given sufficient information, in a way that they understand, to enable them to exercise this right and make informed decisions about the care that they receive. But, as prescribers, we need to assess how much information is sufficient. A further consideration is how we can establish if a patient has truly understood what he or she has been told. A question that we may ask of ourselves in prescribing practice is: Can we actually guarantee that a patient's autonomy is protected when there appears to be no failsafe method of ensuring that consent is indisputably informed? In effect, could we be seen to be proceeding with what should be viewed as 'uninformed consent'.

Jones et al (2005) identified that information giving is variable depending on the individual circumstances of the situation, but confirmed that it is significant enough a dilemma to warrant further exploration. Leading case law provides us with guidance on the limits and extent of information giving and truth telling in the consent process, and non-medical prescribers should not shy away from exploring the law in order to gain a deeper insight into the complexities of their practice. There are leading cases such as *Chatterton v Gerson* 1981 in which it was established that:

... once the patient is informed in broad terms of the nature of the procedure which is intended, and gives consent, that consent is real.

However, as Jones et al (2005) highlight, some practitioners may deduct from the above ruling that a limited amount of information is sufficient in interpreting 'broad terms', yet others may decide that significantly more information is required in order to guarantee that consent is truly valid. Perhaps we need to use our own informed clinical judgement to interpret the true meaning of 'broad terms' and apply our judgements accordingly in individual circumstances. In *Sidaway v Bethlem Royal Hospital Governors* 1985, a neurosurgeon failed to disclose a very remote complication of paraplegia (<1%) in the surgical procedure to which the claimant had consented. The patient's claim for damages was rejected and the court held that 'consent did not require an elaborate explanation of remote side effects'. This said, in prescribing, we are duty bound to offer the patient information about the potential side effects of the prescribed treatments. In both step 3 'consider the choice of product' and step 4 'negotiate a contract' of the NPC (1999) *Prescribing Pyramid*, disclosure and discussion of the side effects are an essential component. A patient's consideration of these side effects will often influence their decision to accept or refuse the suggested treatment. Using the judgment in *Sidaway*, it would seem that it is the practitioner's prerogative to determine to what depth the remote side effects of treatments are discussed with individual patients.

It could be argued that patients are protected by the law and the Human Rights Act 1998, and Article 5 of the European Convention on Human Rights and Biomedicine of 1997 ('the Convention') states that 'an intervention in the health field may only be carried out after the patient has given free and informed consent to it' (Garwood-Gowers et al 2001). Not only are we concerned with the ethical principles of upholding the prescriber/patient relationship here, but also the legal implications of the prescriber being liable for not adhering to the required guidelines for obtaining consent, should we fail to do so. Article 5 clearly addresses patient autonomy and recognises that consent can be withdrawn at any time without penalty. However, there are exceptions to this, in that, should consent be withdrawn during a procedure, and withdrawal of consent results in a situation that contravenes a practitioner's professional standards and obligations, then it does not have to be honoured (Garwood-Gowers et al 2001). An example of this may be when a prescriber has commenced life-saving treatment and withdrawal of consent would interfere with their obligation to preserve life. Ethically, we, as prescribers, would need to decide if this would be the right or wrong thing to do, and the ethical principle of deontology is discussed later in the chapter to offer clarity to the argument. This exception to the rule, however, appears to make a mockery of patient autonomy, in that patients are allowed to exercise self-determination only up to a certain point should a practitioner's professional obligations be considered more significant.

Article 6 of the Convention provides safeguards for the protection of those individuals who are unable to consent for themselves to medical interventions. It is stated that, if an individual does not have the capacity to consent to an intervention because of mental disability, disease or other similar reason, then authorisation can be legally obtained from a responsible person or body. However, the opinions of the patient should be taken into account as far as possible. In the case of a child, authorisation is given by the adult who is legally responsible for that child, yet the opinion of the child is increasingly being sought, depending on the age and degree of maturity of the individual. But are children able to make 'informed' decisions? And who is to say that the adult with responsibility for that child is actually acting as their advocate, or in their 'best interest', and not solely just for their own benefit, or to satisfy their own agenda?

Wager et al (1995) acknowledged that, although it is essential to gain patients' consent when entering into a professional relationship, it is not a simple task. This could possibly be explained by the apparent complexity of the issues involved, or even the reluctance of healthcare professionals to look deeper into the intricacies of the principles of consent. Jones (1999), in citing the *Sidaway* case, acknowledges that, despite the numerous cases involving informed consent, judges have remained conservative in their approach to setting standards for the health professions. As such, it would appear that they remain content to allow the continuation of substandard and potentially unlawful practice in some situations. However, common law dictates that the autonomy of the patient should be protected, by ensuring that health professionals satisfy certain standards of disclosure (Kuhse and Singer 2001). These standards of disclosure were developed within the realms of common law over the last two decades in order to guarantee that the healthcare professional had adequately informed the patient in cases where there was some doubt. The standards have been used solely for the purpose of redress within the law, yet there has been some legislative progress in recent years to provide

guidance to practitioners regarding what to tell their patients before medical interventions (Appelbaum P, Lidz C and Meisel A 1987 - cited in Kuhse and Singer 2001). Young (1990) - cited in Kuhse and Singer 2001, p. 442) suggests there are certain 'elements of disclosure' for informed consent that include:

- the nature of the procedure (or treatment)
- the risks involved
- the alternatives
- the benefits of the proposed treatment.

It would be fair to say that these elements of disclosure should be applied as a *minimum* standard when gaining consent from our patients in a prescribing context. In a landmark case, that of *Chester v Afshar* 2005, the claimant was awarded damages when it was held, in a House of Lords decision by a three to two majority, that insufficient information had been given before surgery which resulted in the potential risks of the particular surgery being realised. The principles of the judgment in *Chester* can be applied effectively to prescribing practice in that it is essential for prescribers to adequately inform patients of the potential risks, interactions, contraindications and side effects of a chosen medication. Failure to provide adequate information would be deemed negligent and prescribers could find themselves in a court of law, defending their practice and decision-making.

Wager et al (1995) further suggest that, before giving consent, patients require information about their illness, the treatments available, the proposed management plan, the effect on their condition and the alternative choices available to them. This does not always happen in practice because anecdotal evidence suggests that the information given to patients is largely dependent on the particular prescriber. There are huge discrepancies in both the *amount* and the *quality* of information that patients receive, despite agreed protocols being in place. As prescribers, we need to consider whether we can ever precisely assess the level of understanding of an individual and whether this can be done with absolute accuracy in all cases. Appelbaum and Grisso (1988, cited in Wager et al (1995), Fitten (1993, cited in Wager et al 1995), Fulford and Howse (1993), Kaveller-Jones et al (1993), Kessel (1994) and the GMC (1998) all acknowledged a multitude of factors that may impact on a patient's level of understanding and suggest that healthcare professionals cannot assume that, because individuals appear to fully comprehend the information given to them, they fully understand the consequences. Furthermore, they advise that the ability of the patient to repeat or regurgitate the information told to them as a means of assessing understanding is not the same as truly appreciating its consequences, and the technique should be used cautiously. For the patients who appear to have a degree of understanding within the realms of their own abilities, but do not understand to the same level of our own mental capacity, can it then still be considered ethical to proceed with prescribing, even if they give their consent? Is this truly 'informed consent'? We could argue that it is informed consent, because consent has been given within the limitations of their own understanding. As prescribers, if we always endeavour to obtain consent within the sphere and extent of a patient's understanding, we could argue, and defend our judgement by saying that it is truly informed.

It could be argued that patients are protected by the law and the Human Rights Act 1998, and Article 5 of the European Convention on Human Rights and Biomedicine of 1997 ('the Convention') states that 'an intervention in the health field may only be carried out after the patient has given free and informed consent to it' (Garwood-Gowers et al 2001). Not only are we concerned with the ethical principles of upholding the prescriber/patient relationship here, but also the legal implications of the prescriber being liable for not adhering to the required guidelines for obtaining consent, should we fail to do so. Article 5 clearly addresses patient autonomy and recognises that consent can be withdrawn at any time without penalty. However, there are exceptions to this, in that, should consent be withdrawn during a 'procedure, and withdrawal of consent results in a situation that contravenes a practitioner's professional standards and obligations, then it does not have to be honoured (Garwood-Gowers et al 2001). An example of this may be when a prescriber has commenced life-saving treatment and withdrawal of consent would interfere with their obligation to preserve life. Ethically, we, as prescribers, would need to decide if this would be the right or wrong thing to do, and the ethical principle of deontology is discussed later in the chapter to offer clarity to the argument. This exception to the rule, however, appears to make a mockery of patient autonomy, in that patients are allowed to exercise self-determination only up to a certain point should a practitioner's professional obligations be considered more significant.

Article 6 of the Convention provides safeguards for the protection of those individuals who are unable to consent for themselves to medical interventions. It is stated that, if an individual does not have the capacity to consent to an intervention because of mental disability, disease or other similar reason, then authorisation can be legally obtained from a responsible person or body. However, the opinions of the patient should be taken into account as far as possible. In the case of a child, authorisation is given by the adult who is legally responsible for that child, yet the opinion of the child is increasingly being sought, depending on the age and degree of maturity of the individual. But are children able to make 'informed' decisions? And who is to say that the adult with responsibility for that child is actually acting as their advocate, or in their 'best interest', and not solely just for their own benefit, or to satisfy their own agenda?

Wager et al (1995) acknowledged that, although it is essential to gain patients' consent when entering into a professional relationship, it is not a simple task. This could possibly be explained by the apparent complexity of the issues involved, or even the reluctance of healthcare professionals to look deeper into the intricacies of the principles of consent. Jones (1999), in citing the *Sidaway* case, acknowledges that, despite the numerous cases involving informed consent, judges have remained conservative in their approach to setting standards for the health professions. As such, it would appear that they remain content to allow the continuation of substandard and potentially unlawful practice in some situations. However, common law dictates that the autonomy of the patient should be protected, by ensuring that health professionals satisfy certain standards of disclosure (Kuhse and Singer 2001). These standards of disclosure were developed within the realms of common law over the last two decades in order to guarantee that the healthcare professional had adequately informed the patient in cases where there was some doubt. The standards have been used solely for the purpose of redress within the law, yet there has been some legislative progress in recent years to provide

guidance to practitioners regarding what to tell their patients before medical interventions (Appelbaum P, Lidz C and Meisel A 1987 – cited in Kuhse and Singer 2001). Young (2001 – cited in Kuhse and Singer 2001, p. 442) suggests there are certain 'elements of disclosure' for informed consent that include:

- the nature of the procedure (or treatment)
- the risks involved
- the alternatives
- the benefits of the proposed treatment.

It would be fair to say that these elements of disclosure should be applied as a *minimum* standard when gaining consent from our patients in a prescribing context. In a landmark case, that of *Chester v Afshar* 2005, the claimant was awarded damages when it was held, in a House of Lords decision by a three to two majority, that insufficient information had been given before surgery which resulted in the potential risks of the particular surgery being realised. The principles of the judgment in *Chester* can be applied effectively to prescribing practice in that it is essential for prescribers to adequately inform patients of the potential risks, interactions, contraindications and side effects of a chosen medication. Failure to provide adequate information would be deemed negligent and prescribers could find themselves in a court of law, defending their practice and decision-making.

Wager et al (1995) further suggest that, before giving consent, patients require information about their illness, the treatments available, the proposed management plan, the effect on their condition and the alternative choices available to them. This does not always happen in practice because anecdotal evidence suggests that the information given to patients is largely dependent on the particular prescriber. There are huge discrepancies in both the *amount* and the *quality* of information that patients receive, despite agreed protocols being in place. As prescribers, we need to consider whether we can ever precisely assess the level of understanding of an individual and whether this can be done with absolute accuracy in all cases. Appelbaum and Grisso (1988, cited in Wager et al (1995), Fitten (1993, cited in Wager et al 1995), Fulford and Howse (1993), Lavelle-Jones et al (1993), Kessel (1994) and the GMC (1998) all acknowledged a multitude of factors that may impact on a patient's level of understanding and suggest that healthcare professionals cannot assume that, because individuals appear to fully comprehend the information given to them, they fully understand the consequences. Furthermore, they advise that the ability of the patient to repeat or regurgitate the information told to them as a means of assessing understanding is not the same as truly appreciating its consequences, and the technique should be used cautiously. For the patients who appear to have a degree of understanding within the realms of their own abilities, but do not understand to the same level of our own mental capacity, can it then still be considered ethical to proceed with prescribing, even if they give their consent? Is this truly 'informed consent'? We could argue that it is informed consent, because consent has been given within the limitations of their own understanding. As prescribers, if we always endeavour to obtain consent within the sphere and extent of a patient's understanding, we could argue, and defend our judgement by saying that it is truly informed.

Silverman (1989) stated that healthcare practitioners are at liberty to ensure that the process of obtaining informed consent is rigorously adopted in order to enable patients to make autonomous choices and assert personal preferences for the treatment on offer. This supports the Kantian view of a patient's right to autonomy and the view that respecting a patient's autonomy acts as an expression of valuing that patient's ability to make a decision. By respecting patients' esteem as individuals, this allows them the dignity of being 'in charge' of their own lives and allows them to be 'masters' of their own well-being (Hendrick 2000). In prescribing practice, patient participation is high on the agenda. Concordance is more readily achieved if the patient has had the opportunity to participate in treatment decisions by exercising autonomy and giving consent freely. Furthermore, the accuracy of the information that the patient receives impacts greatly on the legality of consent giving, and, should the prescriber fail to provide the patient with correct and evidence-based information, it is suggested that consent could be deemed 'misinformed'.

Activity box 2.8

Look at the patient in case study 2.

What factors would you consider when gaining consent from this patient?
How could you guarantee that the patient consented willingly?

As a prescriber what elements of the consenting process may lead you to consider that the patient is:

- 'uninformed'
- 'misinformed'
- 'informed'.

Consent in adults lacking capacity

As prescribers we interact with many different types of patients, who, as has already been discussed, may be temporarily incapacitated due, for example, to illness, shock or reduced consciousness, or under the influence of drugs or alcohol. More complex cases involve those patients we wrongly assume to lack capacity as in the case of *Ms B v An NHS Trust* 2002 who was ventilated but communicated her wishes to refuse treatment. The court held that the patient *did* have capacity and that the continued artificial ventilation of *Ms B* against her wishes amounted to unlawful trespass. As prescribers, in order to avoid similar situations, we need to be able to establish capacity and assess our patients according to the relevant guidelines. Chapter 4 of the Mental Capacity Act (2005) Code of Practice provides detailed guidance on the assessment of capacity and prescribers should familiarise themselves with the direction contained within it.

The Department of Health (2009b, p. 9) clearly states in its guidance that:

For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question (this will be the patient or someone with parental responsibility for a patient under the age of 18, someone authorised to do so under a Lasting Power of Attorney (LPA) or someone who has the authority to make treatment decisions as a court appointed deputy). Acquiescence where the person does not know what the intervention entails is not consent'.

However, under the Mental Capacity Act 2005 (Section 1(2)), it is stated that a person must be assumed to have capacity unless it is established that he lacks capacity.

Furthermore, the Mental Capacity Act 2005 defines a person who lacks capacity as:

- a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain. It does not matter if the impairment or disturbance is permanent or temporary.

The Department of Health guidance (2009b, p. 9) and the Mental Capacity Act 2005 also advise that a:

- person lacks capacity if:

- they have an impairment or disturbance (for example a disability, condition or trauma or the effect of drugs or alcohol) that affects the way their mind or brain works, and
- that impairment or disturbance means that they are unable to make a specific decision at the time it needs to be made ...

The prescriber's responsibility lies with their skill and competence to assess whether or not the patient meets the criteria contained within the Mental Capacity Act and the Department of Health guidance. To further channel our assessment of patients in our care, we should consider the Department of Health (2009b, p. 9) guidance that:

An assessment of a person's capacity must be based on their ability to make a specific decision at the time it needs to be made, and not their ability to make decisions in general. A person is unable to make a decision if they cannot do one or more of the following things:

- understand the information given to them that is relevant to the decision
- retain that information long enough to be able to make the decision
- use or weigh up the information as part of the decision-making process
- communicate their decision – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

Chapter 4 of the Mental Capacity Act 2005 explains what is meant by the terms 'capacity' and 'lack of capacity' (Dimond 2008) and lists the following as examples of an impairment to the functioning of the mind or brain:

- conditions associated with some forms of mental illness
- dementia
- significant learning disabilities
- the long-term effects of brain damage
- physical or medical conditions that cause confusion, drowsiness or loss of consciousness
- delirium
- concussion after head injury
- the symptoms of alcohol or drug use.

As can be seen from the examples in this list, some conditions may cause permanent impairment, yet others may cause a transient or temporary lack of capacity that warrants the prescriber to act in the person's best interest. Similarly, some patients may have the ability to decide what clothes to wear or what food to eat, but lack the ability to make more major decisions such as whether or not to accept or refuse treatment (Dimond 2009).

It could be argued, thus far, that the assessment of a person's capacity to consent or refuse treatment is time-consuming and complex. Do we, as prescribers, always allow sufficient time for such assessment? Is sufficient time always available to us? It is suggested here that often our assessment of capacity is based almost subconsciously on the presenting demeanour of the patient before us. Often, we as prescribers know our patients well and a prior judgement has been made regarding the patient's mental ability. However, in some situations, e.g. in a walk-in centre, an accident and emergency department or a pharmacy, the patient is quite likely to be unknown to us and this is where an assessment needs to be made. Frequently, as experienced practitioners, a formal evaluation of mental capacity is unnecessary, but, where there is doubt or uncertainty, the prescriber should use the available published directions. It should be remembered that, although we strive for equality and tolerance as healthcare practitioners, we must never assume that a person lacks capacity simply because of unsociable acceptable behaviour, a person's appearance, an inability to speak the same language, or indeed by the person's age or appearance. Moreover, as stated in Principle 3 of the Mental Capacity Act 2005:

A person is not to be treated as unable to make a decision merely because he makes an unwise decision.

There will always be cases in our prescribing careers where we do not agree with a patient's decision. If the person is fully autonomous and has sound mental capacity, it is our duty to respect and support that decision while truthfully guiding and informing the patient of the consequences of his or her decisions. No other adult can consent on behalf of a fully competent adult with intact mental capacity.

Having looked at consent in adults with or without mental capacity, we turn our attention to the nuances and complexities of gaining consent in children and young people. All prescribers who work with such patients need to gain a comprehensive knowledge of the legalities of consent, parental rights, and the rights of healthcare practitioners, medics and courts in order to prescribe with appropriate insight and safety. It is sug-

gested that prescribers working with children, as with adults, do not always place sufficient emphasis on the importance of safeguarding the interests and rights of children or indeed protecting them and their interests in clinical situations. To this end, this section directs the reader to certain texts, cases and guidelines that should be read as an adjunct to the chapter.

Consent in young people aged 16 or 17 years

The BMA (2001) advocated that more autonomy should be given to children and young people and that they should be granted more influence and be given the right to be heard in respect of their own decision-making. It was suggested that less credence should be bestowed on paternalism in favour of more participation and involvement, yet, although this appears to be the ideal, the concept can and should be applied only on an individual basis. Furthermore, in prescribing practice, there appears to be significant limitations to this model, particularly in view of the knowledge that children and young people mature emotionally, developmentally, psychologically and cognitively at dissimilar rates. Under the Family Law Reform Act 1969 Section 8(1), a young person aged 16 or 17 years has a statutory right to give consent to any surgical, medical or dental treatment. There is an assumption, however, that the young person has the capacity to do so and where a young person may have learning disabilities, for example, this right can be invalidated. There are circumstances where the consent of a 16- or 17-year-old young person can be overruled, e.g. if the decision that the young person makes is not in his or her 'best interests', parents can seek to make the child a ward of court, yet the courts would always endeavour to take account of the young person's opinion and wishes.

Consent in children aged under 16

The BMA (2009) acknowledge that, in law, there is no presumption of competence for young people aged under 16 and those under this age must demonstrate their competence by meeting certain standards set by the courts. In England, Wales and Northern Ireland, the central test is whether the young person has 'sufficient understanding and intelligence to understand fully what is proposed'. In Scotland, a young person is considered competent to make treatment decisions if he or she is 'capable of understanding the nature and possible consequences of the procedure or treatment' (BMA 2009).

The Family Law Reform Act 1969 states that a parent has a right to give consent to treatment and examination on behalf of a child or young person aged under 16 years. Furthermore, although the parent may have both the right and the duty to act in the child's best interests, the parent may be prosecuted for failure to do so, particularly if the child is harmed as a consequence. Despite this parental right, the law states that the parents' decisions can be overridden in certain circumstances in order to save the life of a child. It is argued that parents' rights to act in their child's best interests was entrenched in law 'long before autonomy and privacy were pervasively applied to incompetent patients and minors' (Beauchamp and Childress 2001) and it was assumed that parents would always act responsibly as advocates for their child. The law established that no intervention in these parental rights would arise, unless there were extreme

circumstances whereby the state and the parents disagreed about a treatment or non-treatment that may have devastating consequences for the child. Under the Children Act 1989 the court has the power to override any lack of consent from parents with a paramount consideration being stated as the overall welfare of the child (Alderson and Goodey 1998).

The Children Act 1989 is the main source of law for the care of children and young people under the age of 18 years and they ultimately come under the inherent jurisdiction of the High Court (Dimond 2008). Although there is no statutory right for a child under the age of 16 to give consent to treatment, the Children Act focuses on the principle that the child's welfare is paramount and stipulates that, provided that the child possesses the necessary understanding to consent to medical examination or treatment, the court should take account of 'the ascertainable wishes and feelings of the child concerned, considered in light of their age and understanding'.

It is important therefore to establish that when making treatment decisions for the under 16s that the child's capacity to consent has been considered. As a consequence of the *Gillick v West Norfolk and Wisbech Area Health Authority* 1985, the House of Lords' ruling was that a child under 16 years of age is able to give valid consent to examination or treatment if he or she is deemed to possess the requisite mental capacity to make the specific decision. This is known as 'Gillick competent', yet, in recent years, the term has been replaced (at the request of Mrs Gillick) by the term 'a child competent according to Lord Fraser guidelines'. In clinical practice, the term 'Fraser competent' is widely used, particularly in the provision of contraceptive services to the under 16s without parental consent. The criteria for a child to be deemed Fraser competent are the following:

- The girl would, although under 16, understand the doctor's advice.
- The doctor could not persuade her to inform her parents or allow them to inform the parents that she was seeking contraceptive advice.
- She was very likely to have sexual intercourse with or without contraceptive treatment.
- Unless she received contraceptive advice or treatment her physical and/or mental health were likely to suffer.
- Her best interests required the doctor to give her contraceptive advice, treatment or both, without parental consent.

In a non-medical prescribing context, the use of Fraser guidelines are particularly useful in determining 'what strategy' to adopt when using the NPC (1999) prescribing pyramid as a model. Although the criteria refer to 'the doctor' throughout, the terms 'pharmacist', 'nurse' or 'allied health professional' can be transcribed to take account of the non-medical prescribers' role in treating the under 16s. It should be remembered, however, that even if a child argues that he or she is 'Fraser competent' the courts would still insist on administering life-saving treatment if necessary. Even though a child may be considered 'Fraser competent', e.g. in *Re E* 1993, this allows only for children to opt in to treatment and not out of treatment. This case involved a 15-year-old boy whose refusal to give consent to a blood transfusion on religious grounds was overruled by the courts in that the judge gave the hospital the authority to administer treatment against both the boy's and the parents' wishes as Jehovah's Witnesses. It was held that,

despite the boy's apparent intelligence and ability to make decisions, the courts felt that he lacked the capacity to understand what the transfusion would involve. The decision was therefore made on the grounds that the welfare of the child was the paramount consideration. Moreover, under Section 8 (3) of the Family Law Reform Act 1969 the statutory powers that exist to allow a child aged 16 or 17 years to give valid consent do not abrogate the ability of those under 16, with adequate maturity, to give legally valid consent to treatment (Wilson 2005).

It is clear from the extensive literature and the arguments presented that truly informed consent, autonomy and mental capacity are difficult to quantify, not only in the child and incapacitated person, but in *all* individuals. It is evident from our examination of the complexities of the issues at stake that we, as prescribers, need to adopt reliable procedures to gain consent, protect autonomy and assess capacity when undertaking prescribing decisions and clinical interventions. Obtaining a comprehensive understanding of the statutory definitions and the guidelines available to us is of utmost importance.

Activity box 2.9

To assess your learning, look at each of the case studies at the back of the book in turn, and consider what factors you would need to take into account in order to guarantee that you obtained legal consent from the patients presented.

Lasting power of attorney

The Government (2010) identify a lasting power of attorney (LPA) as a legal document that appoints a deputy to act on a person's behalf should he or she lose capacity. The MHA (2009) highlight in their guidance that under the Mental Capacity Act in England and Wales, those aged over 18 years can make an LPA by appointing a 'welfare attorney' to make health and personal welfare decisions on their behalf if capacity is lost. They state that the Court of Protection may also appoint a deputy to make these decisions, yet neither welfare attorneys nor deputies are at liberty to demand treatment that is clinically unsuitable. The Mental Capacity Act also requires doctors to consider, as far as is reasonable and practicable, the views of the patient's primary carer. Similarly, in Scotland, the Adults with Incapacity (Scotland) Act 2000 allows people aged over 16 years to appoint a welfare attorney who has the power to give consent to medical treatment when the patient loses capacity. The Court of Session can also appoint a 'welfare guardian' on behalf of an incapacitated adult. Northern Ireland law differs somewhat, in that no person can give consent to medical treatment on behalf of another adult. Interestingly, the views of primary carers or nearest relatives have no legal status in terms of actual decision-making. Therefore, as the law currently stands, doctors may treat an incapacitated person without consent, provided that the treatment is necessary and in the patient's best interests. However, it is identified in law to be good practice for healthcare practitioners to attempt to consult with relatives in order to reach a 'best interest' decision. It is clear that, in prescribing, it is necessary to abide by the laws of

the country in which you practise and be aware of the dissimilarities that exist between the countries of the UK.

Advance directives

Advance directives or 'living wills' are written decisions made in advance of the autonomous person becoming non-autonomous. They exist to express the wishes of the individual in the event of serious decisions having to be made about treatment or end-of-life choices in the event of them losing the ability to be autonomous. Although, in law, the content of advance directives is not legally binding, but is considered by medics and lawyers, the BMA and Law Society (2004) discourage patients from making such directives. There are some legitimate arguments against the use of advance directives such as the claim put forward by Robertson (1991, cited in Herring 2008, p. 182), in which it is suggested that:

The values and interests of the competent person no longer are relevant to someone who has lost the rational structure on which those values and interests rested.

Here it is implied that people with dementia who prepared advance directives could not have predicted how they may feel once their situation changes. Some theorists have gone so far as to suggest that a person with Alzheimer's disease, for example, who prepared an advance directive with his or her critical interests at stake, no longer has the capacity to understand and his or her critical interests should not 'be given any weight' (Dresser 2003). Controversial as it seems, prescribers may potentially be presented with an advance directive dilemma. It is suggested that legal guidance be sought in order to proceed with or without treatment.

Prescribers as advocates

When patients have not yet developed, cannot develop or lose their ability to make treatment decisions for themselves, advocates can be called upon to make substituted judgements on their behalf (Vig et al 2006).

Advocacy can be described as:

The process of identifying with and representing a person's views and concerns, in order to secure enhanced rights and entitlements, undertaken by someone who has little or no conflict of interest.

Henderson and Pochin (2001)

In examining this definition of advocacy, it is suggested that as prescribers, we are in a unique position to represent patients in respect of 'securing enhanced rights and entitlements'. All patients are entitled to receive fair, equitable and timely treatment for conditions affecting them and our ability to prescribe goes some way to ensure that this fundamental right is attainable. In children, advocacy is usually entrusted to an adult with parental rights and, in most cases, this allegiance proceeds without conflict. In adults, however, although it has been suggested that the optimal standard for

advocacy-based decisions is those decisions made by family members, 'best interest' decisions can, and are, made effectively by others including medical practitioners, nurses and the courts. In clinical practice, there are countless situations where the non-medical prescriber will be called upon to make treatment and management choices for their patients and a significant component of working in a prescribing role is to develop the competence and confidence to recognise when advocacy is required, and perform that task responsibly. Advocacy-based decisions are usually made in prescribing practice by means of consultation between families and clinicians, yet the courts will intervene if any disagreements arise.

It should be recognised that, although family members are seen as the ideal advocates, there are significant limitations in this assumption, in that family surrogates are not always ideal representatives for patient preferences (Kirschner KL 2005, cited in Vig et al 2006). Empirical studies in relation to end-of-life care, for example, have shown that the ability of family members to accurately predict patients' treatment choices is markedly flawed, not least because the decisions made are a more precise representation of their own preferences rather than the patients' (Hardwig 1993). However, Hardwig (1993) further identified that many patients still want family members to make decisions on their behalf, even though they realise that the responsibility for decision-making may be a burden and any resulting outcomes will have to be lived with thereafter.

Vig et al (2006) identified a number of ways that family surrogates plan for and make decisions on another's behalf. They highlighted that two-thirds made judgements based on conversations around future care preferences that they had had with their loved ones, yet decisions were often made without the benefit of substantial discussion. This research indicates that the family surrogates do not intentionally disregard the wishes of their family members, and moreover find it difficult to isolate their own perspectives when making decisions for others. Interestingly, some family advocates have relied heavily on previously written advance directives, without much regard for the content, until such time as they are required. As a result, the content has not been explicit and the surrogate has been unprepared for the decisions to be made. A further dilemma can arise where the decision-making process is further complicated by family members' disagreement and this may create a predicament for the prescriber.

Activity box 2.10

Read the following scenario and consider the following:

As a prescriber acting as the patient's advocate, what factors do you need to consider in order to ensure that you are acting legally?

Mr Jones is terminally ill with cancer of the lung and brain metastases. He is widowed and his daughter lives in Australia. However, she intends to travel home in the next few days. Mr Jones is being nursed at home with the help of the district nurses, his son and a very capable family friend. Mr Jones lacks capacity and has increasing pain in his back. You have been asked to review his pain relief but his son and daughter disagree about how Mr Jones should be managed.

Consent is a continuous process and should be sought with each consultation. In supplementary prescribing, for example, it is necessary to confirm that the patient is still in agreement with the devised clinical management plan and that there have been no changes in consent or that any new clinical developments have occurred (BMA 2009).

Confidentiality, sharing information and data protection

For a more comprehensive understanding, this section should be read together with the Department of Health publication *Confidentiality: NHS code of practice* (DH 2003c). In this document it is stated that:

A duty of confidence arises when one person discloses information to another (e.g. patient to clinician) in circumstances where it is reasonable to expect that the information will be held in confidence. It:

- (a) is a legal obligation that is derived from case law
- (b) is a requirement established within professional codes of conduct
- (c) must be included within NHS employment contracts as a specific requirement linked to disciplinary procedures.

As healthcare practitioners we are accustomed to maintaining patient confidentiality. It is a fundamental aspect of healthcare, the principles of which are no less important in prescribing practice. Confidentiality of patient information is of utmost importance for trust to be achieved. The Department of Health (2003c) further identify that 'the patient information we obtain in practice is generally held under legal and ethical obligations of confidentiality and any information provided in confidence should not be used or disclosed in a form that might identify a patient without his or her consent'. Disclosure of confidential information may, in certain circumstances however, be beneficial to patients, e.g. it is often necessary for a prescriber to inform other healthcare professionals, such as the patient's GP, of the treatments prescribed, stopped or dose amended, in order to avoid inadvertent duplication of medicines or the subsequent prescribing of drugs that may interact. Patients should be informed that disclosure of information is necessary for their care to remain safe and anecdotally most patients are satisfied with this requirement. Certain prescribing situations may be more difficult to manage in respect of confidentiality and prescribers working within these areas should ensure that local confidentiality guidelines are adhered to. It is an expectation in prescribing situations that patients divulge personal and often sensitive information in order to be treated effectively. The Department of Health (2003c) recognises that patients entrust and allow NHS personnel to gather information relating to their health and personal matters as part of seeking treatment, yet they hold a legitimate expectation that staff will respect this trust. Furthermore, even if a patient is unconscious or incapacitated for any other reason, this does not diminish the duty of confidence that we have as professionals. It is essential, if the legal requirements are to be met and the trust of patients is to be retained, that the NHS provides, and is seen to provide, a confidential service (DH 2003c).

Following the Caldicott Report 1997, the Department of Health appointed Caldicott guardians to protect patient information (DH 1998). These are senior staff within health and social care who have responsibility for ensuring that patient information and records remain confidential. The Department of Health has produced a manual detailing the methods and responsibilities of Caldicott guardians (DH 2010) in their remit of protecting the sharing of patient-identifiable information between NHS organisations and non NHS bodies. Prescribers should have an awareness of strategic information protection alongside relevant legislation that is necessary to attain comprehensive knowledge of the principles of confidentiality (Table 2.8).



Activity box 2.11

How would you manage confidential information in the following situations? When would it be legally and ethically acceptable to share information?

A 15-year-old girl requests 'emergency contraception' over the counter after unprotected intercourse the previous evening. During the consultation it transpires that she was sexually assaulted a month ago and contracted gonorrhoea.

Jean is 49 and has just been diagnosed with a genetically inherited degenerative condition. You are her physiotherapist and are discussing the rapid progression of the disease. She does not want her estranged children to be told of her diagnosis, but this would mean that they would not have the opportunity to be screened.

A 59-year-old man with diabetes receives treatment from you for erectile dysfunction and a titration of his metformin was also necessary to improve his glycaemic control. He is adamant that he does not want his GP to be informed because he is a family friend.

You have been asked to treat a 24-year-old man for a laceration that he sustained to his hand 20 minutes ago. It becomes apparent that a member of staff has had her purse stolen from the office where the window was smashed.

The daughter of one of your deceased patients has requested a copy of her mother's hospital records.

Gary is 21 and taking methadone prescribed by his GP for a heroin addiction. He attends the pharmacy on a daily basis where the dose is given and ingested at the counter in full view of the general public.

Consider what is the relevance of the Freedom of Information Act 2000 to prescribing practice?

Reducing harm, risk assessment and avoiding litigation

As a prescriber, failure to provide sufficient relevant information to patients, prescribing without due consideration being given to guidelines and evidence bases and failing to obtain valid consent could all be challenged in law. It is suggested in Figure 2.3 that, by

Table 2.8 Current legislation related to the confidentiality and accessibility of patient information

Data Protection Act 1998	The Data Protection Act governs the processing of personal data about all living people in the UK. It sets out principles for information handling with which all data controllers must comply. Its remit includes access to health records of living people, and patients' rights to have inaccurate information corrected
Access to Health Records Act 1990	This Act has mostly been superseded by the Data Protection Act 1998, and now governs only access to the health records of deceased people
Access to Medical Reports Act 1988	This Act governs access to medical reports produced about patients by a clinician
Human Rights Act 1998	Article 8 establishes a right to 'respect for private and family life'. This underpins the duty to protect the privacy of individuals and preserve the confidentiality of their health records. Current understanding is that compliance with the Data Protection Act 1998 and the common law of confidentiality should satisfy Human Rights requirements
Freedom of Information Act 2000	The Act creates a general right of access, on request, to information held by public authorities and creates exemptions from the duty to disclose information. The Act also establishes the arrangements for enforcement and appeal

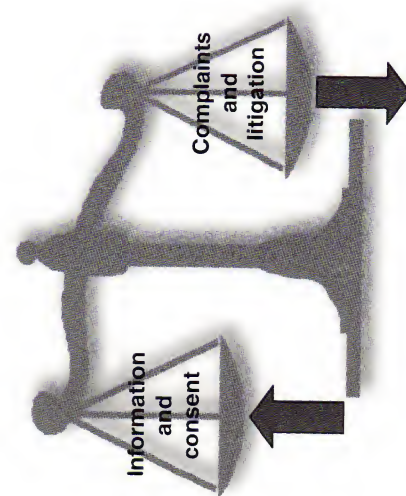


Figure 2.3 Reducing the risk of litigation.

increasing the information we impart to our patients and obtaining consent, we may reduce the probability of potential complaints and litigious proceedings being brought against us.

It is therefore suggested that, in order for the prescriber to minimise harm to their patients and avoid litigious proceedings, careful risk assessment should become a fundamental component of expert practice. Information giving and gaining consent, regular auditing of prescribing practice and accurate, detailed documentation and record keeping are all factors that should be incorporated as standard practice in prescribing. Effective risk assessment also includes personal professional development, evidence-based practice and ensuring that the patient is aware of your prescribing status. It is suggested that, if patients are not aware of the limitations of your prescribing position and harm results, they are more likely to complain than had they known and agreed to be treated by you.

The Medical Defence Union (MDU 2007) identify that drug prescription errors, dispensing errors and the incorrect administration of medication are common causes of adverse incidents and death of patients. They suggest a checklist for reducing risk for anyone involved in prescribing, dispensing or administering medication. It is with this knowledge that we propose that prescribers should be aware that common errors are easily avoided and due care and attention throughout the prescribing process will reduce the incidence. Furthermore, experiential testimony suggests that a degree of complacency can often accompany the increasing expertise of the practitioner. Common errors include wrong drug, dose, strength, quantity, duration and frequency, all of which are avoidable with careful prescribing and vigilance. Further errors include prescribing for the wrong patient, incorrect administration, failing to consider drug interactions or contraindications, and replicating mistakes on repeat prescriptions. The MDU (2007) advise that the following checklist be used for risk management:

- Patients must be told about the nature, purpose and risks of any treatment and any alternatives, and be provided with information about side effects.
- Check for known allergies or hypersensitivities, particularly when prescribing antibiotics, and ensure that these are documented consistently, on paper and computerised records.
- Have robust systems in place to review and monitor repeat medication regularly.
- It is advisable to check the correct identity of patients during each consultation and, if possible, before issuing repeat prescriptions.
- If prescribing unfamiliar drugs, check contraindications and side effects.
- When administering vaccines to young children, appropriate authority from someone with parental responsibility should be obtained and documented.
- Ensure that there are appropriate and up-to-date patient group directions or protocols in place, e.g. for child immunisations.
- All drugs should be checked before administration.
- Consider storing drugs with similar names (e.g. Depo-Provera and Depo-Medrone) or of different doses (e.g. 30mg and 10mg ampoules of diamorphine) separately.
- Ensure that there is a system to rotate stocks and dispose of date-expired items.
- Have an adverse incident reporting system in place so that the practice can learn from any mistakes or near misses that do occur.
- Ensure robust record keeping.

As non-medical prescribers, we have gained an insight into the professional and legal aspects of prescribing practice. The final part of this chapter looks at some of the ethical and moral concepts that may impact on your clinical decision-making and subsequent prescribing practice.

PART 3: ETHICAL ISSUES

The study of ethics is essential to healthcare practice, yet the term is not always easy to define. In addition there are numerous associated terms including morals, rights, duties and obligations that may be confusing to the reader. However, it is suggested that, although some healthcare professionals withdraw from the study of ethics, the subject is captivating once the theories become apparent and are practically applied by the practitioner. The purpose of this section is therefore to highlight some of the more established principles of healthcare ethics and relate theory to practice for the prescriber.

The BMA (2004) offers a definition of medical ethics as:

The application of ethical reasoning to medical decision-making.

Herring (2008) highlights that this definition is vague and suggests that the question remains unanswered as to *what* medical ethics is about. Edwards and Elwyn (2009), however, offer a more straightforward meaning and suggests that 'morals' and 'ethics' be classed as synonyms in the first instance and then divide the term into three components:

- 1 Personal ethics
- 2 Group ethics
- 3 Philosophical ethics

Personal ethics is perhaps what we all, as individuals, think of initially when asked about morals. It is concerned with the moral values that we have developed from sources such as parents, school, media and religious leaders. It encompasses our opinions on ethical issues and our understanding of what is right and what is wrong. From a prescribing perspective, we know that it is morally right to prescribe pain relief to the patient with a fractured femur, just as we also know that it is morally wrong to withhold pain relief if it is within our power to prescribe and administer it. Edwards and Elwyn (2009) suggest that all people who are able to express a view can articulate an opinion based on personal ethics. Group ethics is different in that it relates to groups of people with a similar set of standards as the term suggests. Looking back at the first part of this chapter, it is clearly evident that groups of healthcare professionals such as nurses, pharmacists and allied health professionals hold similar professional standards to each other and these are regarded as codes of 'professional ethics'. Further to Edwards and Elwyn's (2009) classification, the last sense of the term pertains to philosophical ethics. This component of ethics is concerned with a more academic approach to moral theory, language and analysis, knowledge of which is necessary to solve ethical dilemmas.

As prescribers, ethical dilemmas may occur on a daily basis and it is suggested that we draw upon a combination of personal, group and philosophical ethics to assist us in

our decision-making, e.g. if a patient refuses to take the life-saving medication that you have prescribed, you may be guided by your own personal beliefs and values (such as your belief in the sanctity of life), your professional code of conduct and your knowledge and analysis of ethical theory (such as consequentialism or deontology).

Consequentialism

This ethical theory is based on making decisions from a 'common-sense' perspective by looking at the consequences of the action (Edwards 2009). Consequentialists believe that, when faced with two courses of action, the morally right action to take is the one that has the more favourable consequence. Consequentialism can be viewed as 'goal based' in that the rightness or wrongness of actions depends on their consequences and this means that the 'right' or 'moral' thing to do is the one that produces the best possible outcome and the greatest pleasure. The best-known form of consequentialism is utilitarianism (Edwards 2009). Utilitarians, perhaps the most famous being John Stuart Mill (1806-73), advocate that the most important outcome when choosing two opposing pathways is that which results in people being happy. They would also champion the philosophy of 'the greatest good for the greatest number'. In other words, to tell one person to save 100 others can be justified by utilitarians because the greater number of people experienced pleasure as a result. Furthermore, a utilitarian would consider that the action of telling the truth to a patient would be very dependent on the consequence of that truth.

Deontology

Kuhse and Singer (2001) identified that deontology originates from the Latin 'deon' meaning 'duty'. The deontologist believes that there are fundamental rules that should be followed *whatever* the consequences and that duty and obligation are central, rather than what the effect will be. In contrast to utilitarians, it is a fundamental rule that deontologists tell the truth because it is the right thing to do and not because it will result in happiness. Immanuel Kant is thought to be the leading exponent of deontology.

Virtue ethics

Healthcare practice, including prescribing, involves certain 'virtues' such as kindness, honesty, care, benevolence, compassion, courage, temperance and loyalty as described by Edwards (2009). It is these virtues that enable us as practitioners to perform with compassion and understanding in all interactions with patients, and it is suggested here that it would be difficult to prescribe safely and effectively if a prescriber did not possess experience and virtuous characteristics.

The most influential approach to ethics is known as 'principlism'. Beauchamp and Childress (2001) are perhaps regarded as the most eminent authors on principlism and they argue that there are four equal principles that represent a common morality. These are:

- 1 Autonomy (respect for)
- 2 Beneficence
- 3 Non-maleficence
- 4 Justice.

Respect for autonomy

As discussed in Part 2, respect for autonomy means recognising and respecting people who are entitled to such basic human rights as the right to know, the right to privacy and the right to receive care and treatment. Autonomy refers to a person's ability to come to his or her own decisions and to respect those incapable of autonomy because of illness, injury, mental illness or age. This principle is often regarded as the premier principle in medical ethics due to its overarching association with consent. However, some would argue that there are some legitimate flaws in this principle. Although it is commonly agreed that respect for patient autonomy is fundamentally right and that patient choice is of the essence, sometimes 'choices' cannot be honoured, yet this does not mean that autonomy is not being respected, e.g. as prescribers, we welcome and encourage patient participation in treatment choices. However, if, by respecting a patient's autonomy it becomes evident that their autonomous choice is unacceptable (such as demanding inappropriate treatment), it is well within the realms of the practitioner's judgement to not honour that choice.

Beneficence

This principle is concerned with the duty to 'do good' and maximise good, e.g. becoming the patient's advocate. It refers to the obligation to act in a way that promotes the well-being of others – in other words, act beneficently or with beneficence. From a prescriber's perspective, our aim is always to act in a way that will optimise good for our patients, yet in doing so we may also cause them harm. A good example of this is the administration of chemotherapy. Our aim or obligation with this treatment is to do good for the patient with regard to their recovery and prognosis, yet in doing so we actually harm the patient by exposing them to immunosuppression with the associated risks. However, we act with beneficence as our intentions are honourable.

Non-maleficence

Non-maleficence is closely related to beneficence as seen in the example above. Beauchamp and Childress (2001) assert that the principle refers to the obligation to 'do no harm' or to 'minimise harm'. In the chemotherapy scenario, we can minimise harm in a number of ways, such as prescribing antiemetics to counteract the side effect of nausea and vomiting or by ensuring that the dose of chemotherapy is carefully calculated in order to reduce toxicity.

Justice

The principle of justice is a complex principle closely associated with the law. Justice requires equal treatment of equal cases and equitable distribution of benefits. In other

words, there should be no discrimination on the basis of sex, race, religion or age, for example, nor should there be any inequity in the distribution of resources. In healthcare, patients should, when applying this principle, be treated fairly and equally by practitioners, using a comparable degree of means, funds and assets. Another facet of the principle of justice concerns the 'just' manner in which we are held to account for our misconduct. From a prescribing perspective, should we be seen to intentionally harm our patients, or indeed act outside of our competence, justice will be served within the parameters of UK law.

Campbell et al (2005) suggest that 'professional integrity' be added as another principle here, whereas Edwards (2009) suggests a fifth principle of 'respect for persons'. These will be explained briefly as an adjunct to this section.

Professional integrity

It is suggested that healthcare is 'a growing body of expertise and shared skills' (Campbell et al 2005, p. 13). The expansion of expert practice is dependent on respect for different disciplines but also good collaborative relationships between professions in order that high standards are maintained and competences are shared. What this means for the prescriber is that both expert and novice prescribers are obligated to cooperate with each other for the benefit of the patient and the progression of the skill.

Respect for persons

Edwards (2009, p. 28) reminds us that 'all human beings are persons' and that, when considering the first principle of respect for autonomy identified by Beauchamp and Childress (2001), we are obliged to consider that we cannot respect the autonomy of a non-autonomous person. Personhood has been discussed at great length over the years and Harris (1985) controversially suggested that non-autonomous human beings such as babies, those with dementia and people in persistent vegetative states (PVS), for example, are human beings but not persons. Whatever the view of the prescriber, it reminds us to act as that individual's advocate and in their best interests.

Best interests

The 'best interest' principle has been referred to throughout this chapter, yet we need to ascertain what actually constitutes 'best interests'. The 'best interests standard' is widely used in healthcare where patient autonomy is absent. The risks and benefits are weighed against each other in order to conclude a definitive way forward for that individual. Judgements are often based on a 'quality-of-life' criterion in that decision-makers take account of formerly autonomous patients' preferences and values. In other words, previously drawn-up express wishes of the patient are respected and the opinions of others are sought. Advance directives, legal advocates and LPA orders are all considered in best interest and 'quality-of-life' determination. Prescribers who find themselves in the position of having to make such decisions on behalf of their patients should be aware that, according to the Mental Capacity Act Code of Practice (2005), the Act does not actually define the term 'best interests', but instead provides a checklist of factors that must always be taken into account in a situation where a decision is

being made for a person lacking capacity. These factors have been broadly summarised as follows:

- Equal consideration and non-discrimination
- Consider all relevant circumstances
- Consider if the person may regain capacity
- Permit and encourage the person's involvement
- Special considerations for life-sustaining treatment
- The views of other people (where practicable and appropriate)
- The person's wishes and feelings, beliefs and values, particularly where these are written down.

It is important to remember that this checklist does not define best interests as such, is not exhaustive and should be used as a guide only.

As prescribers, in addition to treating acute conditions in the normally well patient, we may be called upon to care for patients who are vulnerable, such as very old or very young people, those living with long-term conditions, terminally ill individuals and those in the last stages of life. Although some practitioners may never prescribe for such patients, it is important to highlight certain ethical concepts that are relevant to all prescribing situations. Those concepts include acting beneficently, within the law, in the person's best interests and with compassion. One of the interesting concepts that we should consider as prescribers is the doctrine of double effect and this is discussed here in the context of end-of-life care as an example.

Doctrine of double effect

Spiritual opinion aside, death is generally viewed as a normal and natural progression to the end of life, yet we are aware that death can be premature, hastened or forced through illness, accident, personal choice or unlawful acts. Within the healthcare professions, death that is anything other than an inherent physiological process can be subject to validation, certification and scrutiny for the protection of the public and the professional alike (Royal College of General Practitioners 2003) (covered in the Coroners Act 1988). In healthcare, the death of a patient, even when expected or inevitable, is rarely unremarkable and, rightly or wrongly, a combination of professional, moral, ethical and legal rules applies. It is the application of these rules that sometimes generates distinct and confusing arguments, often resulting in conflict among medics, ethicists and lawyers. Combining law and ethics can be contradictory and confusing, because legal rules and philosophy do not always sit comfortably together. So what does this mean for the prescriber? Put simply, this means that, as prescribers, our choice to prescribe, what we prescribe, our mode of delivery and our prescribing intentions are all open to scrutiny, e.g. some may view our action to prescribe opiates for our patients as nothing more than a means of shortening or abruptly ending that person's life. Furthermore, this could be applied to everything that we prescribe for our patients: Are we acting beneficently or with maleficence? Can we always justify our decisions? Are we acting with criminal intentions?

Emotive terms such as 'killing someone' or 'allowing someone to die' are fraught with ambiguity and also attract moral, ethical and legal questions that warrant clarification and explicit examination in the prescribing context. It is essential to the discussion that individual determinants and variables such as religious beliefs, moral values, ethical stance, professional obligation and personal position are recognised as being integral to the interpretation of such contentious terms as these. However, in the UK, 'the law is the law' – it exists to guide us, and its foundations are enshrined in ancient Christian tradition, despite our contemporary multi-religious society. Should a prescriber be called to account in a court of law, it is with these Christian principles that the law decides whether their actions were lawful, illegal or otherwise. The doctrine of double effect (DDE), which is also referred to as the principle of double effect (PDE), the rule of double effect (RDE) or 'the doctrine', has its historical roots in mediaeval Catholic moral theology, first developed and articulated by Saint Thomas Aquinas (1225–1274) and later adapted for use in secular discussions in moral philosophy and applied ethics (Hovie 2006). Today, the application of the DDE in modern medicine is distinctly evident. In simple terms, the DDE states that (Kennedy and Grubb 2000, Beauchamp and Childress 2001, Montgomery 2003, Mason and Laurie 2006, Bass 2006):

... If by doing something morally good (such as giving high doses of opiates to relieve pain) has a morally bad side effect (the person's death is hastened), it is ethically acceptable to do so, providing the bad side effect (death) was not the primary intention, even if the practitioner foresaw that the bad effect would probably happen ...

However, it is sometimes impossible to act beneficently to patients without also causing them some harm, because almost all treatments have side effects. It may also be necessary to do something to a patient that would be harmful and wrong outside of a medical context, such as injecting large doses of opiates, yet it is allowed in healthcare because it will ultimately benefit the patient, despite causing harmful effects. To this end, in prescribing practice, the DDE is accepted and applied by many practitioners when undertaking medical decision-making. However, the use of the doctrine may be called into question in English law. Its legitimacy may be called upon to support or oppose a practitioner's defence, particularly where discrepancies in the intentions of that healthcare practitioner are questioned, or where justification and endorsement of an action or omission is required.

Examples of such situations have included caring for patients in the terminal phase of life in *Airedale NHS Trust v Bland* 1993. Williams (1957), in his text on the subject of the sanctity of life, criticised the DDE and argued that the basis for this statement of the law should be challenged and condemned. However, in modern healthcare practice, the law should be challenged from some ethicists, the DDE is still considered to be an established rule of law that is frequently applied in the courts (*Airedale NHS Trust v Bland* 1993; *R v Moor* 2000; *R v Cox* 1957). However, Williams' argument is feasible in the context of prescribing in that, as nurses, pharmacists and AHPs, it is well within our remit to kill the pain without killing the patient. As prescribers, it is paramount, therefore, that we always endeavour to prescribe treatments that are morally, ethically and legally permissible, in order to safeguard our patients, with the primary objective of acting with the best of intentions.

Conclusion

The aim of this chapter was to enlighten the prescriber of the significant importance of professional, legal and ethical concepts that are essential to prescribing practice. Some of the theoretical material incorporated within the chapter may be new to the reader, yet, I would suggest, of fundamental importance in the cognitive development of prescribers. The first part of the chapter has allowed prescribers to consider the relevance of working within their respective codes of conduct and reflect on professional responsibility and accountability. Secondly, prescribers have been given the opportunity to identify with and amalgamate legal theory and practice in order to enlighten them to the safety mechanisms and potential pitfalls of being a prescriber. It is anticipated that the prescriber armed with legal knowledge will progress into a cautious yet prophetic practitioner with advanced proficiency and skill. The final part of this chapter looked at providing the prescriber with moral and ethical theory that is pertinent to their practice. It is anticipated that the reader will use critical reflection as a means to analyse medical ethics in the context of prescribing and ultimately apply the theories to the care of their patients.

Key themes: conclusions and considerations

Public health	The legal, professional and ethical implications of non-medical prescribing must be acknowledged and understood by the non-medical prescriber Consider how legal, professional and ethical issues might affect your ability, or willingness, to incorporate public health targets in to your consultations
Social and cultural issues	Ethical and moral codes originate, in part, from social and cultural norms and expectations Consider the possible cultural and social issues that might impact on the patient's autonomy
Prescribing principles	Numerous legal, professional and ethical issues impact on every stage of the prescribing pyramid. This can range from gaining patient consent to assessment through to accurate prescription writing Consider the legal, professional and ethical issues relevant to negotiating a contract with your patients

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Chapter 3 Factors Influencing Prescribing

Val Lawrenson

Learning objectives

After reading this chapter and completing the activities within it, the reader will be able to:

- 1 Identify the influences upon non-medical prescribing practice
- 2 Critically analyse the impact of the influences on non-medical prescribing in relation to practice
- 3 Identify and evaluate strategies to address the influences on non-medical prescribing in order to support safe and effective prescribing

Prescribing is a complex activity and each consultation is unique, although common themes may emerge. To ensure patient safety and cost-effective prescribing, the practitioner has to be aware of the many factors that might influence practice. In addition to ethical, professional and legal issues, non-medical prescribing is subject to a variety of other influences that impact on the non-medical prescriber's ability to prescribe safely and effectively. For the purpose of this chapter, consideration of these influences is undertaken in the context of the prescriber, the patient, the product and other professionals. This chapter briefly explores some of the issues related to each of these influences and proposes strategies to overcome related difficulties in order to promote concordance.

The prescriber

Julia Cumberledge clearly recognised the benefits of non-medical prescribing (Department of Health and Social Security (DHSS) 1986) however this appreciation is not always shared. Indeed, despite claims of benefits to prescribers, patients and the organisation (While and Biggs 2004, Jones and Jones 2005), many non-medical

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